

10
No. 89-243

Supreme Court, U.S.
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**In the
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

U.

MEDTRONIC, INC.,

Respondent.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

JOINT APPENDIX

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***Petition for Certiorari Filed August 11, 1989
Certiorari Granted October 10, 1989***

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**RELEVANT DOCKET ENTRIES
DISTRICT COURT**

PLAINTIFF ELI LILLY AND COMPANY		DEFENDANT MEDTRONIC, INC.
		DOCKET NO. 83-5393
DATE	NR	PROCEEDINGS
11/7/83	1	Complaint filed
11/7/83		Jury Trial Demanded
1/9/84	8	Answer of Hahnemann University to complaint and counterclaim, filed.
1/26/84	10	Order dated 1/25/84 that the attached Stipulation and Notice of Dismissal is approved except that paragraph one shall be interpreted only as a recognition between parties that jurisdiction and venue are proper, and not as a judicial determination of either. Deft. Medtronic's motion to dismiss for improper venue is denied, filed. 1/26/84 entered & copies mailed.
2/16/84	11	Medtronic's answer to complaint and counterclaim, filed.
7/9/84	19	Order that pltf's motion to strike defenses from answer and counterclaim is granted in part and denied in part, etc., filed. 7/10/84 entered & copies mailed.
8/3/84	20	Pltf's reply to deft's counterclaim, filed.
1/8/86	24	Order that deft's motion for summary judgment is denied, filed. 1/9/86 entered & copies mailed.

1/10/86	31	Order that all further discovery and proceedings in this litigation are stayed pending a final decision by the U.S. Patent & Trademark Office, etc., filed. 1/10/86 entered & copies mailed.
5/5/87	40	Order that Lilly is hereby substituted for Intec as pltf in this action, filed. 5/5/87 entered & copies mailed.
7/8/87	47	Pltf's brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused, filed. (FILED UNDER SEAL)
7/8/87	48	Pltf's brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused, filed. (FILED UNDER SEAL)
7/8/87	49	Medtronic's memorandum regarding the application of 35 U.S.C. § 271(e)(1) to investigational medical devices, cert of service, filed.
7/13/87	50	Pltf's reply brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused. 35 U.S.C. § 271(e)(1), cert of service, filed.
7/13/87	51	Medtronic's reply to Lilly's brief regarding 35 U.S.C. § 271(e)(1), filed. (FILED UNDER SEAL)
11/12/87	72	Pltf's supplemental brief in support of its position on non-applicability of 35 U.S.C. § 271(e)(1) to the actions of deft, filed. (FILED UNDER SEAL)

11/13/87	73	Reply of Medtronic to pltf's supplemental brief in support of its position on 35 U.S.C. § 271(e)(1), cert of service, filed.
11/19/87	84	Motion of deft Medtronic, Inc. for a pre-trial order on the applicability of 35 U.S.C. § 271(e)(1) to medical devices or in the alternative for partial summary judgment, cert of service, filed.
12/8/87	92	Memorandum & Order that deft Medtronic, Inc.'s motion for partial summary judgment is denied, deft is precluded from presenting at trial evidence regarding the 271(e)(1) defense, filed. 12/8/87 entered & copies mailed.
12/11/87	97	Motion of deft Medtronic, Inc. for certification of the Section 271(e)(1) issue for appeal, cert of service, filed.
12/18/87	99	Order that deft Medtronic, Inc.'s motion for certification of the Section 271(e)(1) issue as decided by this Court in its memorandum & order of 12/4/87 is denied, filed. 12/18/87 entered & copies mailed.
1/4/88	109	Deft Medtronic's pre-trial brief, filed. (FILED UNDER SEAL).
2/9/88	123	Deft Medtronic's pre-trial brief, filed. (FILED UNDER SEAL).
2/10/88	130	Plff's pretrial brief in support of its damage presentation, filed. (FILED UNDER SEAL).
2/10/88	131	Pltf's pretrial brief in support of injunction, filed (FILED UNDER SEAL)
2/10/88	132	Plff's pretrial overview of the case, filed (FILED UNDER SEAL)

2/24/88	160	Civil Jury Trial of 2/23/88, day 1, jurors called and sworn, plff opens, defense opens, plff witness sworn, filed.
2/25/88	161	Civil Jury Trial of 2/24/88, day 2, plff witnesses recalled, witness sworn, filed.
2/26/88	165	Civil Jury Trial of 2/25/88, day 3, plff witness recalled, plff deposition testimony, filed.
2/29/88	166	Civil Jury Trial of 2/26/88, plff witness' sworn, filed.
3/1/88	170	Civil Jury Trial of 2/29/88, jurors present, plff witness testifies, filed.
3/2/88	171	Trial resumes 3/1/88, Pltf's Witnesses sworn, filed.
3/4/88	173	Trial resumes 3/3/88, jurors present, pltf's witness sworn, plff deposition of Michael Kalluk read to jury, defense counsel moves the Court for a directive verdict refused by Court, defense witness sworn, filed.
3/4/88	174	Trial resumes 3/4/88, defense witness recalled, defense witness sworn & recalled, filed.
3/8/88	175	Trial resumes of 3/7/88, etc, filed.
3/8/88	176	Supplemental Report of Special Master filed.
3/10/88	179	Trial resumes 3/9/88; defense counsel moves for a mistrial - C.A.V., etc., filed.
3/11/88	183	Trial resumes 3/10/88, filed.
3/14/88	186	Jury trial resumes 3/11/88; Deft's motions for a mistrial is hereby refused by the Court, etc., filed.

3/14/88	187	Deft's Memo re: Revised Proposed Jury Instructions; Objections to Certain Lilly Instructions; & Responses to Lilly's objections, filed.
3/15/88	188	Trial resumes of 3/14/88, filed.
3/16/88	189	Jury trial resumes of 3/15/88, filed.
3/16/88	190	Medtronic's further objections & comments with respect to Lilly's revised proposed jury instructions, filed.
3/16/88	193	Trial resumes 3/16/88; Deft's move for Directed Verdict - Court ruled - Motion is hereby refused, filed.
3/16/88	196	Plaintiff's brief in support of injunction during extension of the '757 patent, filed.
3/22/88	201	Special Interrogatories to the Jury, filed.
3/22/88	202	Trial resumes 3/21/88; Court charges Jury, filed.
3/23/88	204	Trial resumes 3/22/88, filed.

3/24/88	205	Trial resumes 3/23/88, deliberations continue. Verdict in favor of plfff & against the deft in the amount of \$26.5 million per Special Interrogatories to the jurors, filed.
3/24/88	206	Special Interrogatories to the Jury & Answers, thereof, filed.
3/25/89	208	Argued Sur 3/25/88 re defendant Medtronic post trial brief on issue of inequitable conduct and plaintiff response for injunction relief, C.A.V., filed.
3/25/88	213	Memo in opposition to Injunctive Relief, filed.
4/1/88	218-240	Transcripts of Jury Trial, filed. (23 Vols.)
4/4/88	241	Order that deft's motion for mistrial is hereby refused & in explanation of the order, filed. 4/4/88 entered and copies mailed.
4/18/88	244	Argued Sur: Hearing on 4/15/88 re: Pltf's request for injunctive relief is granted. Order will be filed.
4/18/89	245	Defendant's objections to proposed form of injunction, cert. of serv., filed.
3/19/88	246	Plfff's Posttrial Memo Regarding Enforceability of Patents in Suit, filed.
4/19/89	247	Plaintiff's post trial brief in support of injunction, cert. of serv., filed.
4/20/88	248	Pltf's brief in support of increased damages, cert of serv, filed.
4/21/89	249	Plaintiff's response to Medtronic's objections to proposed form of injunction, cert. of serv., filed.

4/21/88	250	Pltf's brief in support of an award of attny fees & expenses pursuant to 35 U.S.C. Section 285, cert of serv, filed.
4/21/89	251	Plaintiff's brief in support of prejudgment interest, cert. of serv., filed.
4/21/88	252	Memo & order that US Patents No. 27,757, reexamined & issued as B1 Re. 27,757, No. 3,942,536, reexamined & issued as B1 3,942,536 are valid and enforceable: judgment is hereby entered in favor of plfff Eli Lilly & Co. & against deft Medtronic, Inc. in the amt of \$26,500,000, plus an additional royalty of \$166,000 totalling \$26,666,000, filed. 4/21/88 entered and copies mailed.
4/21/88	253	Order that having made findings of fact & reached conclusions of law of record on 4/15/88 and having concluded on 4/21/88, there was no inequitable conduct, the motion of Eli Lilly & Co. for injunctive relief against deft Medtronic, Inc. is granted, filed. 4/21/88 entered & copies mailed.
4/22/88	254	Defendant Medtronic's motion for stay of this court's injunction pending appeal, Memo, cert. of serv., filed.
4/27/88	256	Plaintiff's brief in opposition to defendant's Motion to Stay Injunctive Relief, cert. of serv., filed.
5/2/88	265	Transcript of Court's Findings of Fact & Conclusions on 4/15/88, filed.
5/3/88	266	Order that deft Medtronic, Inc.'s motion for stay pending appeal of Court's injunction entered 4/21/88 is denied, filed. 5/4/88 entered and copies mailed.

5/5/88	267	Medtronic's motion for judgment notwithstanding the verdict as to Claim 4 of U.S. Patent Re. 27,757, memo, cert of serv, filed.
5/5/88	268	Medtronic's motion for judgment notwithstanding the verdict on the question of willful infringement, memo, cert of serv, filed.
5/5/88	269	Medtronic's motion pursuant to Rule 62(B) to stay execution of judgment pending disposition of post-trial motions, memo, cert of serv, filed.
5/5/88	270	Medtronic's motion under Rule 50(B) for judgment of reduced damages notwithstanding the verdict, memo, cert of serv, filed.
5/5/88	271	Medtronic's motion for a new trial, memo, cert of serv, filed.
5/5/88	272	Medtronic's contingent motion for a stay of execution of judgment pending appeal, memo, cert of serv, filed.
5/12/88	275	Deft's notice of appeal sent to Federal Circuit Court of Appeals, filed. 5/13/88 copies: R. Schneider, Esq., H. Jacobson, Jr., Timothy Malloy, Esq., Clerk, USCA, Judge Ditter, D. Spitz.
5/12/88	275(a)	Copy of Clerk's Notice to Federal Circuit Court of Appeals, filed. (USCA Fed Cir. #88-1409)
6/23/88	288	Order that Defendant Medtronic's, Inc.'s unopposed motion to stay execution of judgment pending disposition of post-trial motions is granted. Judgment contained in Court's 4/21/88 order stayed pending disposition of all pending motions under Rule 50, 52(B) and 59 filed, filed.

4/3/89	305	Defendant Medtronic's Motion to Clarify or stay the injunction of 4/21/88, memo, cert. of serv., filed.
4/6/89	306	Errata sheet for Medtronic's memo in support of motion to clarify or stay the injunction of 4/21/88, filed.
4/11/89	307	Lilly's Memo in opposition to Medtronic's Motion to clarify or stay the injunction of 4/21/88, cert. of serv., filed.
4/13/89	308	Plaintiff's supplemental brief in opposition to Medtronic's motion to clarify or stay the permanent injunction, cert. of serv., filed.
4/14/89	309	Hearing of 4/14/89 re defendant's motion to clarify or stay injunction of 4/21/88, C.A.V., filed.
4/17/89	310	Order that deft's motion to clarify or stay injunction of 4/22/88 is denied, filed. 4/17/89 entered and copies mailed.
6/9/89	312	Defendant Medtronic's renewed motion for interim clarification or stay of injunction of 4/21/88, cert. of serv., filed.
6/16/89	315	Lilly's response to Medtronic's renewed Motion for interim clarification or stay of the injunction of 4/21/88, cert. of serv., filed.
6/19/89	316	Medtronic's reply to Lilly's response to Medtronic's renewed motion for interim clarification or stay the injunction of 4/21/88, cert. of serv., filed.
6/27/89	317	Plaintiff's response to court's proposed form of injunction, filed.
6/28/89	318	Order that Medtronic's renewed motion for interim clarification is granted in part & injunction entered 4/21/88 is modified, etc, filed. 6/28/89 entered and copies mailed.

8/7/89	321	Medtronic's Memo re: scope of new trial in light of Federal Circuit decision, filed.
8/17/89	322	Order that a hearing shall be held to determine whether deft is entitled to the defense provided in 35 U.S.C. 271(e)(1). Decision on Medtronic's post-trial motions shall be withheld until conclusion of hearing. On 9/6/89 a phone conference shall be held to discuss the scheduling of hearing, filed. 8/17/89 entered and copies mailed.
8/24/89	323	Medtronic's formal objection to and Motion for reconsideration of Order of 8/16/89, and memo, certificate of service, filed.
9/6/89	324	Lilly's memo in opposition to Medtronic's Motion for Reconsideration of the order of 8/16/89, filed.
9/19/89	325	Pre-trial conference memo—9/7/89, filed.
9/20/89	326	Medtronic's memo re scope of Fed.R.Evid. 104 Hearing and Conditional Request clarification.
10/23/89	327	Plff's motion for an Order to show cause why Medtronic should not be held in contempt for directly violating paragraphs 1 & 3 of the injunction DTD 4/21/88 as modified on 6/28/89, Memo, Cert. of Serv., filed.
10/25/89	328	Order that by 11/3/89 Medtronic will file response to Lilly's Motion for an Order to show cause why Medtronic should not be held in contempt for directly violating court's injunction orders. On 11/16/89 at 10 A.M. Hearing will be held on Lilly's contempt motion, on 10/3/89 at 2 P.M. a pretrial telephone conference will be initiated from chambers, filed.

**RELEVANT DOCKET ENTRIES
COURT OF APPEALS**

**PLAINTIFF-APPELLEE
ELI LILLY AND
COMPANY**

**DEFENDANT-APPELLANT
MEDTRONIC, INC.**

DOCKET NO. 88-1409

DATE	NR	PROCEEDINGS
5/12/88		Notice of appeal filed by the Defendant in the District Court. (1c)
6/6/88	1	Appellant's motion for stay of injunction pending appeal, filed. (SD-6/3-M).(bam) (SEE ORDER DATED 7/28/88).(bam)
6/13/88	3	Appellee's brief in opposition to appellant's motion to stay injunctive relief (also exhibits 1 thru 40, attached), filed. (SD-6/11-M).(bam) (SEE ORDER DATED 7/28/88).(bam) * <u>[CONFIDENTIAL]</u>
7/25/88		BRIEF FOR THE APPELLANT, filed. (SD-7/25-M)(cr)
7/28/88	8	IT IS ORDERED: Medtronic's motion for stay pending appeal is DENIED.(per PN).(bam)
8/31/88		SUGGESTION FOR HEARING IN BANC filed by appellant (SD-8-30-M). mym 8-31-88: SOP 18 circulated. 9-20-88: SOP 18 (response) circulated. DECLINED: 10-6-88 9/7/88 BRIEF FOR THE APPELLEE, filed. (SD-9/6-M) (jb)

9/14/88 9 Appellee's motion for leave to file a brief opposing the suggestion for hearing in banc (brief in opposition attached), filed. (SD-9-13-M). (bam) (EOD 9/16/88) GRANTED: 9/20/88. (per df on 9/19/88). (bam)

9/23/88 REPLY BRIEF FOR APPELLANT & SEPARATE JOINT APPENDIX, filed. (Separate Joint Trial Exhibits (4 copies)) (SD-9/23-M) (jb)

10/18/88 11 Appellee's motion for leave to file surreply brief instanter (reply brief attached), filed. (SD-10/17-M).(bam) DENIED: 10/28/88 (per df at direction of panel)

10/31/88 13 Appellant Medtronic's errata to reply brief citation, rec'd. (SD-10/31-H). (bam) (EOD 11/2/88)

11/3/88 ARGUED. (Nies, Archer, JJ, and Cowen, SJ) dw

11/3/88 Court has requested counsel for both sides to submit brief in 15 days, not to exceed 10 pages (due 11/18/88). (per JH) (df)

11/18/88 SUPPLEMENTAL BRIEF FOR THE APPELLANT, filed. (SD-11/18-M) (jb)

11/18/88 SUPPLEMENTAL BRIEF FOR THE APPELLEE, filed. (SD-11/17-M) (jb)

11/23/88 17 Appellee's supplemental citations relating to recent statutory amendments to 35 U.S.C. sections 156(b) and 271(e)(1), rec'd. (SD-11/23-M). (bam) (EOD 11/29/88) (Circulated to panel on 11/29/88).(bam)

3/2/89 18 Appellee's citation of supp auth, rec'd. (Cir to the panel.) (MS-3/2) (scg)

3/3/89 19 Appellant's citation of additional authority, rec'd. (FS-3/3).(bb) (Circulated to panel on 3/7/89).(bb)

3/29/89 REVERSED AND REMANDED. (Nies, J.) "JUDGMENT ENTERED" (lrp) Each party shall bear its own cost. 872 F.2d 402

4/7/89 20 Appellant - Motion to expedite issuance of the mandate. (MS-04/06/89) Filed: 04/07/89. Reply 1 (21) Filed: 04/10/89. Action on Motion (20): Denied by merits panel. Filed: 04/11/89. (EOD 04/11/89) (88) 88-1409

4/11/89 APPELLEE'S PETITION FOR REHEARING AND SUGGESTION FOR REHEARING IN BANC, filed (SD-4/11/89-M). (Id) SOP 16 circ. 4-14-89. (Id)

25 Appellant's supplemental citation of recent congressional action relating to 35 U.S.C. Sec. 271(e)(1). (Circulated to panel on 4/12/89) (MS-04/11/89) Received: 04/12/89 (EOD 04/12/89) (88) 88-1409

26 Zimmer/Bristol - Motion of Zimmer, Inc. and Bristol-Myers Co. for leave to file a brief as amici curiae in support of petition for rehearing and suggestion for rehearing in banc. (MS-04/12/89) Filed: 04/12/89. Action on motion (26): Granted by merits panel. Filed: 04/14/89. (EOD 04/14/89 by 88) 88-1409

27 Hatch/Moorhead - pro se motion of amici curiae, The Hon. Sen. Orrin G. Hatch and the Hon. Represen. Carlos J. Moorhead under Fed. R. App. P 29 for leave to file the accompanying brief amicus curiae in the above identified appeal. (MS-

04/12/89) Filed: 04/12/89. Reply 1 (20) Filed: 04/17/89. Reply 2 (29) Filed: 04/20/89. Action on motion (27): Granted by merits panel. Filed: 04/17/89. (EOD 04/21/89 by 88) 88-1409

30 Appellant - Medtronic's motion for relief under Fed. R. App. P. Rule 8(a) from injunction of April 21, 1989. (MS-04/20/89) Filed: 04/20/89. Action on motion (39): Denied by merits panel. Filed: 04/24/89. (EOD 04/24/89 by 88) 88-1409

32 Ventritex, Inc. - Motion of Ventritex, Inc. for leave to file a brief as amicus curiae in opposition to petition for rehearing and suggestion for rehearing in banc. Not served. Filed: 05/01/89. Action on motion (32): GRANTED by merits panel. Filed: 05/10/89. (EOD 05/10/89 by 88) 88-1409

33 Telectronics - Motion of Telectronics, Inc. for leave to file a brief as amicus curiae in opposition to both the petition for rehearing and suggestion for rehearing in banc. (MS-05/01/89) Filed: 05/01/89. Action on Motion (34): GRANTED by merits panel. Filed 05/4/89. (EOD 05/4/89 by 88) 88-1409

5/1/89

APPELLANT'S ANSWER TO PETITION FOR REHEARING & SUGGESTION FOR REHEARING EN BANC, filed (S.D. - 5/1/89-M). (1d) SOP 16 (response) circ. 05-02-89. (1d).

35 Procter/Gamble - Motion by the Procter & Gamble Company for leave to file a brief amicus curiae in support of petition for rehearing and suggestion for rehearing in banc after 14-day period for filing such brief. (MS-05/05/89) Filed: 05/08/89. Action on Motion (36): DENIED by merits

panel. Filed 05/25/89. (EOD 05/25/89 by 88) 88-1409

36 Pfizer Hospital - Motion by Pfizer Hospital Products Group, Inc. and Pfizer Inc. for leave to file a brief amici curiae in support of petition for rehearing and suggestion for rehearing in banc after 14-day period for filing such brief. (MS-05/23/89) Filed: 05/26/89. Action on motion (36) DENIED by merits panel. Filed 05/30/89. (EOD 05/30/89 by 88) 88-1409

5/31/89 Appellee's Petition for Rehearing DENIED: 505-31-89. (1d) SOP 18 Circ. 05-31-89. (1d).

37 Amer Sterilizer - Motion by American Sterilizer Company for leave to file a brief amicus curiae in support of petition for rehearing and suggestion for rehearing in banc out of time. (MS-05/31/89) Filed: 05/31/89. Action on motion (37). DENIED by merits panel. Filed: 07/17/89. (EOD 07/17/89 by SCG) 88-1409

38 Appellees - Lilly's motion to enlarge the time before issuance of the mandate under Fed. R. App. P. 41(A) or, in the alternative, to stay issuance of the mandate under Fed. R. App. P. 41(B). (MS-06/05/89) Filed: 06/05/89. Reply 1 (38) Filed: 06/06/89. Action on motion (38): The Motion is Denied by merits panel. Filed: 06/08/89. (EOD 06/08/89 by 88) 88-1409

6/8/89

MANDATE ISSUED TO THE ED/PA. (LC)

7/18/89

Appellee's Suggestion for Rehearing In Banc DECLINED: 07-18-89 (1d) PUB. CORRECTED ORDER DECLINING with dissent by PN. (1d)

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

Eli Lilly and Company,
Plaintiff,

v.

Medtronic, Inc.,
Defendant.

Civil Action No. 83-5393
Before the Honorable
J. William Ditter, Jr.

DECLARATION OF PETER BARTON HUTT

1. I am a partner in the Washington, D.C., law firm of Covington & Burling, specializing in food and drug law and in government regulation of health and safety. From 1971 to 1975, I was Chief Counsel for the United States Food and Drug Administration (FDA). I am co-author of *Food and Drug Law: Cases and Materials* (Foundation Press 1980), serve on the editorial board of the *Food Drug Cosmetic Law Journal* and several other journals, and have published numerous papers on food and drug law. My curriculum vitae accompanies this Declaration.

2. I have first-hand knowledge of the provisions and legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (DPC-PTR Act), which was enacted on September 24, 1984. In particular, I represented the Pharmaceutical Manufacturers Association (PMA) during the negotiations among divergent industry groups and members of Congress over the content and language of the Act. PMA is a voluntary nonprofit association of over 100 companies that are responsible for discovering, developing, manufacturing, obtaining FDA approval of, and selling almost all of the pioneer prescription new drugs in this country.

3. I make this Declaration in support of plaintiffs' memorandum supporting nonapplicability of 35 U.S.C. § 271(e)(1) to Medtronic's infringing devices. This Declaration is based on my personal recollection of the events leading to enactment of 35 U.S.C. § 271(e), the language and legislative history of the provision, and documents embodying a contemporaneous interpretation of the scope of the provision.

(a) During the approximately two years of consideration of this legislation, I was personally involved in drafting, and in meetings and telephone conversations concerning principal provisions of, the legislation. In addition, our Firm compiled a legislative history of the Act.

(b) Based on my personal knowledge, just prior to enactment I prepared a contemporaneous summary of the legislation. In late 1984 I co-authored an extensive memorandum for our pharmaceutical industry clients on the Act and its implications. On the basis of that, I co-authored an article on the Act that was published in July 1985, "Balancing Competition And Patent Protection In The Drug Industry: The Drug Price Competition And Patent Term Restoration Act of 1984," 40 Food Drug Cosmetic Law J. 269 (1985).

(c) All of these documents represent contemporaneous interpretations of the Act and, in particular, of the legislative intent underlying some of the more ambiguous statutory provisions. Such contemporaneous documentation is extremely important in resolving controversies over interpretations of the Act, because the legislative history is relatively sparse and fails to elucidate some of the Act's key provisions.

4. In addition to representing PMA during consideration of the DPC-PTR legislation, I served as counsel for PMA before the United States Court of Appeals for the Federal Circuit and the United States Supreme Court when PMA appeared as *amicus curiae* in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F. 2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984). In that case, the Federal Circuit held that the testing of a patented drug to meet FDA approval requirements, before the expiration of a valid patent, constitutes infringement. This decision was overruled by Section 202 of the DPC-PTR Act, which added Section 271(e) to Title 35 of the United States Code. This statutory provision and the underlying legislative intent are at issue in the case before this Court.

OVERVIEW OF DPC-PTR ACT PROVISIONS

5. Title I of the DPC-PTR Act established the procedures under which the FDA may approve applications for generic versions of pioneer new drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act requires every person who wishes to market a new drug to submit a new drug application (NDA) demonstrating the safety and effectiveness of the drug before the drug may be marketed. A "full NDA" contains all of the required animal and human proof of safety and effectiveness, accumulated through years of testing. A new drug for which a full NDA is submitted to FDA is called a "pioneer new drug" (or, under the DPC-PTR Act, a "listed" drug). In contrast, a new drug for which approval is sought on the basis that it is equivalent to a previously approved pioneer drug, and for which no animal and human studies on safety and effectiveness are independently conducted, is called a "generic drug." An application to market a generic drug is called an "abbreviated NDA" or "ANDA." Title I of the DPC-PTR Act authorized the submission and approval of ANDAs for an enormous number of human drug products that had not been subject to generic competition before the law was enacted.

6. Title II of the Act restores part of the patent protection lost by new drugs, antibiotic drugs, human biological products, medical devices, and food and color additives as a result of FDA premarket testing and approval requirements. Data presented to Congress have demonstrated that the 17-year patent protection had been seriously eroded for pharmaceutical products. Because of the increase in FDA research, testing, and approval requirements, a drug patent was shown to have a much shorter effective life, less than half the 17 years provided by Congress under the patent law. Title II of the 1984 legislation was designed to restore at least part of the lost patent life for FDA-regulated products.

7. Title II also added 35 U.S.C. § 271(e) to the patent law. Section 271(e)(1) provides as follows:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and

Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

The purpose of this provision was to overrule the decision in the *Bolar* case, and thus to facilitate FDA approval of generic copies of new drugs through the ANDA provisions consistent with the public policy embodied in Title I of the DPC-PTR Act. As described in detail below, it was clear to me, and I believe to virtually all persons who were involved in the consideration of the legislation, that 35 U.S.C. 271(e)(1) was intended to apply only to patented human drug products, not to any other patented invention. The legislation was intended to be extremely narrow and to overrule *Bolar* only as the case applied to patented human drug products.

THE BOLAR CASE

8. In *Roche Products, Inc. v. Bolar pharmaceutical Co.*, Bolar used Roche's patented drug, while the patent remained valid and unexpired, to begin to perform the research required to formulate its own generic drug product. Bolar also used the patented invention to begin to develop the data that must be submitted to FDA in an ANDA in order to obtain approval to market the generic drug product. Bolar asserted that it had the right to encroach upon Roche's patent, without authorization from Roche, for purposes of developing and testing its competitive drug product.

9. The Court of Appeals for the Federal Circuit held that this use by Bolar was an infringement of Roche's patent. The unlicensed use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving it of profits from the sale or licensing of the drug to other drug manufacturers, during the patent term, for whatever development and testing is necessary to satisfy regulatory requirements. The Federal Circuit decision prohibited Bolar from obtaining the benefits of such a sale or license arrangement without authorization from Roche.

10. Bolar also argued that it should be permitted to encroach upon the unexpired patent to develop its competitive product and to perform the tests required for FDA approval of the product so that it could compete with the patented product immediately upon expiration of the patent. It would have taken Bolar approximately two years to copy the pioneer drug, do the testing required, and obtain the expedited FDA approval that existed for generic products. Bolar was asking the Court of Appeals to allow it to encroach upon Roche's valid and unexpired patent for that two-year period. According to Bolar, any other result would extend for two years after patent expiration the monopoly of patent holders in the pharmaceutical industry. The Court of Appeals refused to allow this commercially significant encroachment in the guise of an expanded "experimental use" defense to liability for infringement.

11. The Federal Circuit therefore held that the unlicensed use of a patented human drug for development, testing, and other purposes in order to satisfy FDA regulatory requirements is an illegal infringement.

12. Bolar had argued to the Federal Circuit that public policy favors generic drugs and thus mandated the creation of a new exception to the patent law's prohibition on unlicensed use of a patented product that would apply only to generic drugs. The Federal Circuit declined to create such an exception, which it considered "legislative activity proper only for the Congress." 733 F.2d at 864. In fact, Congress created this special exception for generic human drug products when it reversed the *Bolar* decision through 35 U.S.C. § 271(e)(1) in conjunction with enactment of Title I of the DPC-PTR Act facilitating the approval of generic human drugs.

13. In sum, Title I of the DPC-PTR Act was intended to speed the approval of generic copies of human drug products. Title I did not apply to any other FDA-regulated products. In order to facilitate further this newly adopted public policy, Congress overruled the *Bolar* decision to the extent necessary to allow generic drug manufacturers to develop and test a drug product before expiration of a patent so that the generic manufacturer can compete with the patented drug product immediately upon expiration of the patent. Because Congress

did not enact similar expedited approval provisions for FDA-regulated products other than human drugs, it would be illogical to conclude that Congress intended to overrule *Bolar* for all FDA-regulated products, including medical devices and food additives, or to overrule *Bolar* for all patented inventions. Rather, Congress in 35 U.S.C. § 271(e)(1) was creating a narrow exemption from the patent law's use prohibition to further the specific public policy relating to human drug products that was embodied in the ANDA provisions of Title I of the DPC-PTR Act.

LANGUAGE AND LEGISLATIVE HISTORY OF 35 U.S.C. § 271(e)(1)

14. Section 271(e)(1) is quoted above in paragraph 7. The Section provides that it is not an act of infringement "to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The statutory language itself thus applies to the use of a patented invention to obtain approval under Federal laws regulating *drugs*, not any other type of product. The language omitted in the quote above explicitly states that the provision does not apply to a new animal drug or a veterinary biological product, making it clear that Section 271(e)(1) applies only to *human drugs*. Thus, by its terms, 35 U.S.C. § 271(e)(1) authorizes the use of patented human drug products, without a license, in order to develop, test, and submit a marketing application under Federal laws regulating human drugs. Such laws include the provisions of the FD&C Act that were added by the Drug Amendments of 1962 (including Section 505 of the FD&C Act, 21 U.S.C. § 355), the Biologics Act (42 U.S.C. § 262), and Section 507 of the FD&C Act governing certification of antibiotics (21 U.S.C. § 357). Such federal laws do not include, for example, the Medical Device Amendments of 1976, which added 21 U.S.C. §§ 360c-360k.

15. Further evidence that Section 271(e)(1) applies only to human drug products is found in the other paragraphs of Section 271(e). Paragraph (2) defines as an act of infringement the premature submission of an ANDA to obtain marketing approval for a generic drug before expiration of the patent on the pioneer drug. Paragraph (3) relates back to paragraph (1) in defining

the relief permitted for an act of infringement, and paragraph (4) applies to remedies for infringement of a human drug patent. The intertwining of these four paragraphs indicates that they were all intended to apply to the same type of patented product, namely patented human drug products. Therefore, when viewed in the context of the four provisions of Section 271(e), it is clear that paragraph (1), which reverses the *Bolar* decision, was intended to apply only to human drug products consistent with the other paragraphs of subsection (e).

16. The formal legislative history of the DPC-PTR Act is sparse. The legislation was introduced in the House on July 19, 1983, substantially revised and introduced in the Senate on June 12, 1984, and reported by the House Committee on Energy and Commerce on June 21, 1984 (H.R. Rep. No. 857, Pt. 1, 98th Cong., 2d Sess.). Various provisions of the bill were amended and reported by the House Committee on the Judiciary on August 1, 1984 (H.R. Rep. No. 857, Pt. 2, 98th Cong., 2d Sess.). There is no Senate report on this legislation. Consideration of the legislation and passage by the Senate and House occurred on August 10, September 6, and September 12, 1984. The statute was signed by the President on September 24, 1984.

17. The reports of both House committees indicate that 35 U.S.C. § 271(e)(1) was intended to apply only to patented human drug products, and not to all patented inventions or even all FDA-regulated patented inventions. The Report of the House Committee on Energy and Commerce (p. 45) provides:

"Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section does not permit the commercial sale of a patented drug by the party using the drug to develop such information, but it not does permit the commercial sale of research quantities of active ingredients to such party. The information which can be developed under this provision is the type which is required to obtain approval of the drug."

This description of Section 271(e)(1) focuses solely on the use and approval of drugs. This Committee Report also links the provisions of Section 271(e)(1) with the provisions of Title I. The Report (p. 46) states that Title I permits the filing of ANDAs for generic drugs and "contemplates that the effective approval date will be the expiration date of the valid patent covering the original product." Section 271(e)(1) of Title II was intended to assure that the patent term would not be indirectly extended by requiring generic drug manufacturers to spend two years following expiration of the patent to develop, test, and obtain approval of an ANDA (*id.*).

18. The Report of the House Judiciary Committee also indicates that Section 271(e)(1) applies only to human drug products. For example, in discussing the provision overruling the *Bolar* case, the Report reprints in its entirety an opinion of the Congressional Research Service of the Library of Congress, American Law Division. That Report describes the provision overruling *Bolar* as follows:

"In § 202 [of the DPC-PTR Act], Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA premarketing approval of a drug." H.R. Rep. No. 98-857, Pt. 2, at 27 n.18.

This passage, which was reprinted as part of the House Report, shows that the focus of Section 271(e)(1) was to overrule *Bolar* only to the extent it related to applications for approval of drugs.

19. During a Hearing before the Senate Committee on Labor and Human Resources on June 28, 1984, Professor Norman Dorsen of New York University School of Law submitted a prepared statement in which he reviewed the provision overruling the *Bolar* case to determine if it presented any serious constitutional problems. Throughout his prepared statement, Professor Dorsen discusses the *Bolar* case and its implications solely in terms of human drug products. *Drug Price Competition and Patent Term Restoration Act of 1984*: Hearing on S.2748 Before the Senate Committee on Labor and Human Resources, 98th

Cong., 2d Sess. 179-203 (June 28, 1984). In particular, Professor Dorsen offered this description of the impact of Section 271 (e)(1) on the *Bolar* decision, which clearly indicates his conclusion that it would affect only human drug patents:

"Section 202 of the proposed legislation would reverse the *Bolar* decision in its entirety, not just for the patent involved in that case, but for all existing drug patents. Indeed, the bill would go beyond the infringing conduct involved in *Bolar* by making it lawful for an infringer to make and to sell as well as to use the patented substance during the period of the patent grant, if done for the purpose of securing FDA approval of a new drug. It would also reverse existing patent law by prohibiting courts from issuing an injunction against making, using or selling the substance for that purpose, and it would withdraw from the patentee his current right to collect damages for such infringement."

Id. at 182.

Other portions of Professor Dorsen's statement similarly suggest that Section 271(e)(1) was limited only to drug patents. *Id.* at 180, 181, 198.

CONTEMPORANEOUS INTERPRETATIONS OF 35 U.S.C. § 271(e)(1)

20. As indicated in paragraph 16 above, there is no Senate report on this legislation. The absence of a Senate report is due to the rapidity with which the legislation was ultimately considered, amended, considered again, and enacted. Nevertheless, shortly before Senate passage of the legislation, consideration was given to the issuance of a Senate report. On behalf of PMA, and based on my intensive personal involvement in the negotiations and discussions over the legislation, I prepared a contemporaneous summary of the legislation just prior to its enactment.

21. My contemporaneous summary describes Section 271(e)(1) as follows:

"Section 202 amends section 271 of the patent law to add a new subsection establishing the circumstances under which use of a patented human drug is and is not an infringement of a valid unexpired patent.

"The provision states that it shall not be an act of infringement to make, use, or sell a patented human drug product solely to obtain the information required by FDA to obtain approval of an abbreviated NDA or paper NDA. The provision is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products. If any patented invention were used in violation of the patent in conjunction with the testing of the patented human drug product, this provision would not exempt it from a determination of patent infringement. Thus, a patented calibration device could not be used under this provision in a way that violated the patent even though it was used in conjunction with the permitted testing of a generic drug.

"The intent of this provision is solely to overrule the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that the testing of a patented drug to meet FDA requirements, before the expiration of a valid patent, constitutes infringement. It is therefore extremely narrow. It applies only to a patented human drug product, not to any other invention. It does not allow any patented human drug product to be commercially marketed in violation of a patent. It only allows testing. No generic drug can be sold to a single physician or a single consumer until FDA approves it. No generic drug can be tested or used for purposes other than to obtain data and information required for FDA approval, before the patent expires. The provision, in short, does not give generic manufacturers a license to do whatever they wish before a patent expires. It is intended only to permit the testing essential for FDA approval, at the expense of the generic company."

Neither this nor any other Senate report was issued due to the press of time.

22. I have also explained that Section 271(e)(1) applies only to human drug products in an article published in July 1985, which is referenced in paragraph 3 above. That article states:

"Patent Infringement. New section 271 (e)(1) states that it shall not be an act of infringement to make, use, or sell a patented human drug product solely to develop the information required by FDA to obtain approval of an ANDA or a paper NDA. This provision is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products.

"This provision overrules the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which held that the testing of a patented drug to meet FDA requirements before the expiration of a valid patent constitutes infringement. Because section 271(e) was intended solely to overrule this judicial decision, it is narrow in application. This statutory provision applies only to patented human drug product, not to any other invention. As explained in the House Report, the provision allows testing and experimental activity only for the purpose of developing information which is required to obtain approval of a drug. It does not allow the commercial sale of a patented drug by the person using the patented drug to develop such information." 40 Food Drug Cosmetic Law J. 308.

23. In sum, my contemporaneous understanding of Section 271(e)(1) was that (a) it applies only to human drug products, and not to medical devices or other FDA-regulated products or other patented inventions, and (b) it is narrow in scope in authorizing testing only for the purpose of developing information essential to obtain marketing approval of a generic drug, and does not permit broader commercial activities or use of the patented drug without a license.

24. Besides myself, other members of the food and drug bar and the patent bar who had been closely following enactment of the DPC-PTR Act also interpreted Section 271(e)(1) as being narrow in application.

(a) Alan D. Lourie, Vice President, Corporate Patents and Trademarks, and Associate General Counsel, SmithKline Beckman Corporation (who served as the primary drug industry patent lawyer who worked with me on the legislation and thus was also completely familiar with the development and intended meaning of the Act), published an article entitled "Patent Term Restoration: History, Summary, and Appraisal," 40 Food Drug Cosmetic Law J. 351 (1985), in which he stated:

"One more amendment to the patent laws is provided for by the DPC-PTR Act. Overruling the decision of the Court of Appeals for the Federal Circuit in the case of *Roche Products v. Bolar Pharmaceutical*, the new statute provides that it shall not be patent infringement to make, use, or sell a patented human drug product solely for uses reasonably related to the development and submission of information under a federal law regulating the sale of drugs. Thus, work done formulating and testing a patented drug during the life of the patent in order to be able to file an ANDA is not an infringement." *Id.* at 360.

Mr. Lourie's discussion of the statutory provision clearly focuses on human drug products.

(b) Steven J. Goldstein, Patent Counsel with The Procter & Gamble Company, published a paper entitled "The Drug Price Competition And Patent Term Restoration Act Of 1984 Title II — Patent Extension Provisions," 40 Food Drug Cosmetic Law J. 363, 367 (1985), in which he states:

"The DPC-PTR Act presents the anomalous situation that while the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."

Mr. Goldstein further states that the use of the patented drug

must be reasonably related to the drug approval process, and cannot extend to any and all unlicensed uses. *Id.*

25. Throughout the course of debate on the provision overruling *Bolar* no industry groups other than the drug industry became involved or participated. If any other FDA-regulated industry — such as the medical device industry — had even suspected that the provision overruling *Bolar* would adversely affect their patented products, they would certainly have made their objections known to Congress. This provision was extensively discussed in the trade press. Virtually all of the lawyers involved in the negotiations had clients in the medical device industry and food industry as well as in the pharmaceutical industry. Since all of the other FDA-regulated industry groups were silent on the *Bolar* provision, they obviously understood that 35 U.S.C. § 271 (e)(1) would overrule the *Bolar* holding on the patent law's use prohibition only as to human drug products, and not as to medical devices or other patented inventions.

CONCLUSION

26. Based on my personal knowledge of the statutory provision at issue in this case, my participation in the drafting and consideration of the legislation enacting that provision, and the documentary sources discussed in this Declaration, I conclude that 35 U.S.C. § 271(e)(1) applies only to patented human drug products and does not apply to medical devices or other FDA-regulated products. I further conclude that Section 271(e)(1), in overruling *Bolar*, provides only a narrow exemption for the unlicensed use of a patented human drug product, authorizing only the development of information essential to the approval of an application for marketing a generic human drug product.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on July 3, 1987.

/s/ PETER BARTON HUTT

PETER BARTON HUTT

Medtronic's 1st, 2nd and 3rd Responses To Plaintiff's Interrogatory No. 12

INTERROGATORY NO. 12

12. State whether any application for patent, either U.S. or foreign, has been filed by defendant Medtronic directed to either cardioverters or catheter electrodes; if so, identify each application by country, title, serial number, filing date, name of applicant, and name of inventor. For each such application, state its present status, including its patent number if a patent has issued.

OBJECTION: In addition to the general objections set forth above, Medtronic objects to Interrogatory No. 12 to the extent that it requests information about patent applications other than those which on their face are directed to cardioverters or to the catheter electrodes identified in Medtronic's objection to Interrogatory No. 9, on the ground that the interrogatory is to that extent unduly burdensome and seeks information which is not relevant to the subject matter of this action and does not appear to be reasonably calculated to lead to the discovery of admissible evidence.

ANSWER:

12. Medtronic has filed numerous patent applications on external and implantable pacemakers, pacemaker programmers and pacing leads which disclose or claim technology which is employed in the cardioverters and catheter electrodes identified in response to Interrogatories 7 and 9. Medtronic has attempted to list all such applications which on their face are directed to cardioverters or the catheter electrodes identified in answer to Interrogatory 9, but objects to the identification of other applications for patent as unduly burdensome.

<u>Medtronic No.</u>	<u>Country</u>	<u>Serial No.</u>	<u>Patent No.</u>
P-154	U.S.	125300	Abandoned
P-169	U.S.	235756	3805795
P-169 RE 1	U.S.	901962	Re. 30387
P-169 RE II	U.S.	901963	RE. 30372
P-367	U.S.	140745	Abandoned
P-367	EPO	81102888.5	Pending
P-379	U.S.	58847	Abandoned
P-379	Australia	60666/80	Pending
P-379	Canada	356555	1160296
P-379	EPO	803024132	0023134
P-379	Japan	96156/1980	Pending
P-379 Cont.	U.S.	239007	4403614
P-389	U.S.	58846	Abandoned
P-389 Cont.	U.S.	219254	4375817
P-464	U.S.	374457	Pending
P-464	EPO	83302485.4	Pending
P-499	U.S.	246528	Pending
P-504	U.S.	186368	Abandoned
P-519	U.S.	210656	4355646
P-535	U.S.	215308	Abandoned
P-542	U.S.	262863	Pending
P-542 Cont.	U.S.	499582	Pending
P-544	U.S.	241314	4384585
P-544	U.S.	82301160.6	Pending
P-661	U.S.	577635	Pending
P-674	U.S.	577631	Pending

Answer to Interrogatory No. 12

The list of applications is amended as follows:

<u>Medtronic No.</u>	<u>Country</u>	<u>Serial No.</u>	<u>Patent No.</u>
P-379	Australia	60666/80	538,816
P-464	U.S.	374,457	4,493,325
P-544	EPO	82301160.6	Pending
P-674	Canada	473,574	Pending
P-674	France	85 01 446	Pending
P-674	Germany	P 35 03 854.3	Pending

Plaintiff's Answer and Supplemental Answer to Medtronic's Interrogatory No. 7(k)

INTERROGATORY NO. 7(k)

7. Separately, for each type of automatic defibrillator identified in answer to Interrogatory 6,

(k) State the date of first sale and, by month and year, the number and dollar volume of sales of automatic defibrillators which have been sold by Plaintiffs;

ANSWER

(k) The first sale of the AID was in December 1980. Sales figures, in units and dollars, are as follows:

<u>Year</u>	<u>Units</u>	<u>Dollars</u>
1980	2	12,000
1981	57	306,000
1982	66	507,600
1983	200	1,905,020
1984 (through April)	162	1,540,556

SUPPLEMENTAL ANSWER:

<u>(k)</u>	<u>Period</u>	<u>Units</u>	<u>Dollars</u>
	4/30/84 — 7/31/84	62	\$ 703,041
	6/1/84 — 5/15/85	363	\$ 5,174,000
	5/15/85 — 12/31/85	381	\$ 4.4 million
	1/1/86 — 12/31/86	895	\$ 10.8 million
	1/1/87 — 10/31/87	1825	\$ 23.6 million

DAY 3 TRIAL TESTIMONY OF RICHARD W. STRAIN [Strain — page 30]

'83 device is out, with the '87 timetable, so all these are projections before 1987. They are extremely relevant.

THE COURT: Well, I will sustain the objection insofar as it goes to — if what your plan was to do was to project this

page as a transparency, I will sustain the objection.

However, I will permit you to say what the sales were in '85 and '86 and then you can say that back in '80, whenever they made 24, what did you project for '87.

MR. MALLOY: Good. I will do that.

THE COURT: And I think that the figure for '87 is close enough that that would have some probative value. So I will permit you to do it that way but I will sustain the objection so far as a projection of page 12 of this exhibit is concerned

(Whereupon, the discussion concluded at sidebar.)

BY MR. MALLOY:

Q Can you tell us what Exhibit 205 is?

A Yes, sir. Exhibit 205 was a document prepared in the middle of July, 1984, by CPI in looking at the various issues and potential opportunities of integrating the implantable defibrillator into Cardiac Pacemakers, Incorporated.

Q Now, I would like you to turn to page 12, if you would.

A Yes, sir.

Q And the graph at the bottom of page 12, is that a projection made as of a particular date?

[Strain — page 31]

A Yes, sir. The large craft.

Q Excuse me. Just before you go on. Let's take it just one step at a time. This was a projection of units; is that correct?

A Yes, sir.

Q And units of what type?

A Units of the implantable defibrillator.

Q And was it a projection made as of approximately what date?

A Approximately the middle of July, 1984.

Q How many units did you project to be sold in the year 1987?

A Our projections were approximately 2,500 units.

Q Of what?

A Of the automatic implantable defibrillator.

Q And in terms of market statistics and accuracy, how did reality match up with your projection of 2,500 units in the year 1987?

A Last year we sold 23001 units.

Q And so how would you characterize that in terms of your marketing understanding and accuracy of projections?

A Well, having been in market research for almost 20 years.

MR. HEIST: Objection, Your Honor.

THE WITNESS: I felt pretty comfortable with those estimates.

BY MR. MALLOY:

Q Now, referring to the acquisition of the implantable

[Strain — page 47]

Q Now, we have heard mention of a population of patients who suffer cardiac arrest of 400,000. Are these devices sold to all those 400,000?

A Yeah. Let me discuss that [Strain - page 48] as it relates to the automatic implantable cardioverter defibrillator. In the United States annually, about 400,000 patients suffer from sudden death syndrome and it is called sudden death syndrome because you can't look at me and I can't look at you and determine that you are a candidate. So the typical patient tends to collapse. They collapse either at home, maybe in a hospital, or on the street. So of those 400,000 patients who suffer this sudden loss of consciousness, approximately 20 percent survive. So out of the 400,000, 320,000 die. 80,000 survive.

Of the 80,000 that survive, about three quarters of them can be managed with drugs, or at least it seems so today with current drugs available. So out of the 80,000 patients who have survived

one sudden death syndrome attack, 60,000 treated with drugs, 20,000 are potential candidates for this device because they cannot be managed with drugs. And these are then what we view as the potential candidates for this device, those 20,000 patients.

[Strain — page 52]

recover that right now because I don't think, 532 —

THE COURT: 532?

MR. VOGLER: We haven't referred to that one, have we?

MR. MALLOY: We are about to.

MR. VOGLER: We are about to get to it.

(Whereupon, the discussion concluded at side bar.)

BY MR. MALLOY:

Q Would you refer to Exhibit 532, please.

A Yes, sir.

Q What is Exhibit 532?

A 532 is our latest price list for the cardioverter defibrillator product line specifically.

Q And the product is called what?

A The VENTAK AIC-D.

Q What is the price of that product?

A The price of the device — the price for the PG is \$13,000.

Q PG meaning what?

A Meaning the pulse generator, but the large size of the device. And with its complete lead system would add another 3,000, so the price is somewhere between 15,000 and \$16,000 per device with appropriate leads.

Q In terms of the effect of this device, the AIC-D, automatic implantable cardioverter defibrillator that CPI was able to sell,

what effect financially and specifically did that have on CPI in the last year or two?

[Strain — page 60]

THE COURT: I didn't understand your objection.

MR. MALLOY: My objection is is he asking the witness about what Medtronic has done and not done and I object because Medtronic has withheld as confidential its business information from this witness. I think it is an improper question.

MR. HEIST: Excuse me

(Brief pause.)

MR. HEIST: Your Honor, I am advised that we have not withheld as confidential the number of implants that have been accused.

MR. MALLOY: They withheld all the business information from Medtronic.

THE COURT: Well, I don't know what has been disclosed or what was withheld from this witness or otherwise. If you want to pursue it, I will see you at sidebar. Or why don't you talk about it with each other and see if you can agree upon what you are talking about, because I don't have any information one way or the other.

(Brief pause.)

BY MR. HEIST:

Q Are you aware that Medtronic's devices, accused devices, have not yet received final FDA approval?

A I am aware that no other devices other than ours have received FDA approval.

Q Now, Lilly's commercial product, its defibrillator product, [Strain — page 74] on the upswing and I guess the answer is yes or no.

MR. MALLOY: Well, yes or no with an explanation, Your Honor, which I think would be appropriate.

THE COURT: Well, I think we all know what the answer

will be and so you can ask him when it comes your turn.

MR. MALLOY: Okay.

BY MR. HEIST:

Q Now, I understood you to say that there were 400,000 patients a year who are susceptible to sudden death and that of those, approximately 80,000 — pardon me, approximately 20,000 are candidates for defibrillators?

A Yes, sir, potential candidates.

Q And if I understood your sales figures for 1987, I believe it was, you sold around 2300 defibrillators?

A That is correct.

Q So that's a little bit more than 10 percent of the market?

A Yes, sir, that's true.

Q Now, if you will assume with me that Medtronic has implanted 20 units since 1983, that's about four or five units a year, since that time.

THE COURT: Well, on the average.

BY MR. HEIST:

Q On the average. Do you know what percentage of the market that constitutes?

A No, sir, I don't.

[Strain - page 76]

Q The figure 2300 units which was the figure for 1987, that was the filling of every order CPI received; correct?

A Yes, sir. That is right.

Q Now, 2300 is still less than the 20,000 figure of potential candidates. Why the difference between those two numbers?

A Well, I have used in our forecast and for forecast purposes with a product as invasive as this is — and I guess maybe a little background is necessary here. The FDA approval for this

device basically made it a therapy of last resort. It meant that if a patient could not take drugs and control their problem, then the next step was go through surgical applications, which was a surgical procedure which I will not explain because I don't really have the talent to. And then if that was not successful, then, and only then, would the patient be a candidate for the automatic implantable defibrillator.

It was our very strong feeling that this is very [Strain — page 77] fragile therapy, it is very early in its life, it is very early in its acceptance, and so the fragility of that means that having devices in the marketplace that work, educating the physicians and, as you notice, I had concentrated earlier on talking about the electrophysiologist as the key, a very technical specialist in implanting these devices, well key to him getting patients who are candidates for these devices is also our work with what we call invasive cardiologists that would bring in potential customers to the electrophysiologist for this kind of therapy.

So I think it is safe to say that the therapy is on the leading edge. It is not accepted by all physicians. You can see from the clinical data I shared with you that it is definitely lifesaving, but the specification for the appropriate patient is something that still is emerging. So when I felt, given the product as it is today, there is a potential for 20,000 patients a year to be treated, I still feel very strongly about that. Getting there will take more time and more education on the part of ourselves and on the part of physicians.

DAY 3 TRIAL TESTIMONY OF
MICHAEL M. TOFFOLI
[Page 150]

Q I would like to draw your attention to the third page of Exhibit 139."

MR. MALLOY: Could we have the third page.

"Q And ask you what you are trying to depict by the graph on this page?

A This page basically takes the market projection from the first

page and adds to that projection our, Medtronic's unit plan for PCD's, my expectation of what Intermedics would be [Toffoli - page 151] able to do in the market with their version of a pacemaker, cardioverter defibrillator, and also recognizes that during the early 90's we should expect to see other manufacturers attempting to introduce products and that in all likelihood they will eke out some small volume.

Q Does the graph depicted on the third page of Exhibit 139 show predicted market shares for the companies that you have listed?

A Essentially it does.

Q And that includes predicted market share for CPI?

A That's correct.

Q Did you develop any projected profits for Medtronic for fiscal years '88 through '92 for the PCD units?

A No, I have not done that.

Q Has anyone done that at Medtronic?

A I don't know. I haven't reviewed any documents that looked at — at the — you know, that looked specifically at profit projections over time.

Q Have you heard of any projected profits for Medtronic for any time for the fiscal years '88 through '92?

A I'm not aware of any specific projections.

Q Referring back to the third page of Exhibit 139, what did you use as background information to establish the market share for, market share comparisons for Medtronic, CPI and Intermedics?

[Toffoli - page 152]

A My primary considerations were based on my understanding of product evolution and product introduction likely to occur from each of those three companies over this period of time, coupled with the historical muscle that each of the three companies had demonstrated in terms of sales and marketing of their products.

Q Anything else?

A Those are the two prime ingredients in the projection.

Q Is it fair to say that Medtronic has greater historical muscle than CPI in marketing its products?

A In marketing its pacing products, I think that's definitely true.

Q Is it fair to say that Intermedics has historical — is it fair to say that Intermedics has greater historical muscle in marketing its products than CPI?

A I think that's also true.

Q Is it fair to say that Medtronic has greater historical muscle to market its products compared to Intermedics?

A I believe that's true.

Q What do you mean by the term historical muscle?

A Given somewhat equivalent product lines, what level of a share historically has each company been able to achieve. And if the product lines are essentially equivalent, then the difference in share reflects marketing and sales in service level prowess, coverage, whatever you want to call it.

Q Anything else?

[Toffoli — page 153]

A No.

Q From this graph can you tell me what market share you have estimated for Medtronic in 1/92 — and I presume 1/92 refers to fiscal year '92; is that correct?

A I believe on this chart I was looking at the year beginning in January 1992.

Q Okay. And is that the same for the chart on the first page?

A Yes.

Q On the bottom — referring again to the third page of Exhibit 139, can you give me an estimate of what you projected for the market share of Medtronic for implantable defibrillators starting the year 1/92?

A It would be easy enough to calculate it from the numbers

on the previous pages, but I believe it was somewhere in the area of 40 percent.

Q Do you remember what percentage of market share you predicted that Medtronic would have for implantable defibrillators in calendar year January '94?

A I believe in that year I was assuming we would achieve something around 45 percent. [Toffoli — page 155]

“Q Again referring to the third page of Exhibit 139 under Assumptions, there is a caption Medtronic and under that the language, “achieves current plan, including International release of 7216 summer 1989. U.S. release early 1990 with a transvenous lead during 1990.” What is meant by that entry?

A I think it is fairly straightforward. That is a statement of the assumptions underlying that projection.

Q Does that mean U.S. market release of a PCD unit with a transvenous lead in 1990 or during 1990?

A It means what it says, which in U.S. release of a PCD in early '90 with a transvenous lead during '90. That does not say early '90. There were no and there are no firm plans for that lead, so I did not assume it would be there with the PCD, [Toffoli — page 156] but that it would follow.

Q The U.S. release in early 1990 refers to the 7216 PCD?

A That's correct.

Q And was it your assumption that that would be used with a transvenous lead during 1990?

A Sometime during 1990.

[Toffoli — page 159]

MR. MALLOY: Can we put 142 on the projection?

“A Yes. This is a document that I prepared to communicate to the Medtronic Attendees at the World Pacing Symposium held in Jerusalem in June of this year what our position was regarding tachycardia management products at that medical meeting.

Q What did you intend attend [sic] the Medtronic Jerusalem attendees to do with this document?

A I intended them to read the document and be aware of its contents.

Q Is this document the position of Medtronic to be passed along to Attendees of the Jerusalem conference?”

MR. LEVIN: Objection, Your Honor. This testimony has never been designated.

MR. MALLOY: You designated it. I would be delighted to skip it. In fact, I was going to ask the Judge if I could.

THE COURT: Well, why don't you talk with each other and decide?

MR. MALLOY: I will skip right over it. I am going [Toffoli — page 160] over to line 16 on page 215. The answer at line 16.

“A The document was an internal Medtronic document and only went to Medtronic people.

Q Under item A first A on that first page there is a statement: ‘Medtronic will be the major supplier of implantable defibrillators and external EP stimulators . . . Doctor, your medium/long range partner in tachy control devices is Medtronic.’

What was your intent when you wrote that statement?

A The intent was to communicate to my colleagues that we are, indeed, committed to being a major participant in serving the needs of the electrophysiologists.”

MR. MALLOY: I would like to skip the next two pages, also. You designated them. Do you mind if I skip them?

“Q Under the heading Strategy item A states: ‘Expedite the PCD development and clinical evaluation achieving a releasable International 30 joule system by summer 1989;’ and I ask you, what were the reasons that you had in mind when you used the word ‘expedite’?

A Do everything within our control and resource capability to achieve that system.

Q Why was that?

A Because I think there is a real opportunity there.

Q What type of opportunity?

A The opportunity depicted in the revenue projection that we [Toffoli — page 161] discussed yesterday.

Q And what would be the consequences if you did not expedite that development?

A Revenue projection would be less.

Q That would be the revenue projection for Medtronic?

A Correct.

Q Referring now to item C under 'Strategy,' you state 'short term, leverage education programs and research projects that will build credibility and rep relationships critical to the future success;' and I ask: What is meant by 'leverage education programs and research projects'?

A To utilize educational offerings to the electrophysiologists, and research — joint research efforts with the electrophysiologist, to build contacts, and to determine that we are knowledgeable, credible partner in their tachycardia management efforts.

**DAY 3 TRIAL TESTIMONY OF
JOHN D. ROBERTS
[page 177]**

Q To page 35. "How did you come about your conclusion that you saw a need for the model 7220?"

A Feedback from physicians.

Q What feedback was that?

A The concern that there was no back-up defibrillation.

Q Was there a concern that there was no defibrillation back-up prior to the 7210 going into IDE Study?

A Yes.

Q Have you ever heard any reasons why Medtronic continued forward with the 7210 study despite that concern?

Q Yes.

Q What were those?

A Information would be gathered on the requirements for building a unit that could produce relatively high energy output pulses. In addition, information on detection algorithms for ventricular tachycardia.

Q Do you know if there was ever an intent to market the model 7210?

A To my understanding, there was never an intent to market the 7210.

Q Could you please refer your attention to the third paragraph of Exhibit 153, the second sentence in that paragraph which reads: 'the funds generated by implants of such a product, whether clinical, assuming the precedent set for the first model 7210 is maintained or marketed could be applied to [Roberts — page 178] additional enhancements and future devices.'

Do you see that?

A Yes.

Q Does that refresh your recollection in any way, whether there was ever an intent to market the model 7210?

A Yes.

Q What is your current recollection?

A My current recollection is that even though the word in here indicates that there was some possibility of that, I don't recall anyone ever relating to me that the model 7210 would be marketed.

Q Did Medtronic charge for the model 7210 devices?

A Yes."

Q To page 50. "What was that awareness?"

A On page 50?

Q Line three.

"A. That development of that device was ongoing.

Q Anything else?

A That there was an intent to evaluate it clinically.

Q Anything else?

A Depending upon the outcome of the clinical evaluation, it may or may not be an intent to market the product. That was about it.

Q. When you referred to the outcome of the clinical, were you referring to an IDE study?

**DAY 4 TRIAL TESTIMONY OF
JOHN D. ROBERTS
[page 88]**

"Q Have you ever heard if AICD units would be back-ups for 7215 PCD's?

A Oh, yes.

Q In what circumstances did you hear that?

A I was one of the proponents of that idea.

Q Why was that?

A Well, we were uncertain as to the number of patients that would be able to receive the Model 7215 because of a limited output capability; and since it required an open chest procedure, rather than leave the patient with nothing after opening the chest, it seemed unethical to not provide a back-up unit, and the only back-up unit that could be provided was the AICD.

**DAY 4 TRIAL TESTIMONY OF
DR. RICHARD LUCERI
[page 101]**

Q Did there come a point in time in your career when you heard of Mr. Mirowski?

A Yes.

Q Would you describe that circumstance?

A That was in approximately 1980 when a publication appeared in the New England Journal of Medicine that was authored by Dr. Mirowski and his colleagues presenting their results with

the automatic defibrillator, the first results, I believe, in humans.

[Luceri - page 102]

Q What was your reaction to that publication?

A Well, I was actually quite excited and after reading the article, I thought this was a revolutionary step in the treatment of this disease.

Q Why was that?

A Why was that?

Q Why did you think it was revolutionary?

A Because no one approached the problem in this way before and I think that after reviewing the other data available, for instance, regarding drug therapy or operations, this was the only type of approach that really stopped this problem from happening once it started.

The other methods sought to prevent the occurrence of the problem, in other words, prevent those arrhythmias from starting in the first place, but this was the only concept, to my knowledge, that stopped the arrhythmia from occurring once it started, and that in itself was revolutionary.

Q Were you aware of any criticism of Dr. Mirowski in his invention?

A Yes, I was.

Q And what was that?

A There were numerous criticisms, probably because of the — what I call revolutionary nature of the treatment. It is not unusual in this field, and I guess in all other fields, for something so radical to be ridiculed and I think Dr. Mirowski [Luceri — page 103] underwent a significant amount of ridicule that even appeared in the printed medical literature, which was quite unusual.

Q Did you undertake, after learning of Dr. Mirowski's invention, to contact him or to do anything further with respect to the device?

A Yes, I did.

Q What was that?

A In 1983 I first met Dr. Mirowski. We were at an international meeting in Vienna and the meeting was on pacing and arrhythmia therapy and Dr. Mirowski did not know me, but I obviously knew of him and I approached him and basically established contact with him and asked if I could be an investigator with this device. [Luceri — page 106] detected by these two button electrodes. They sense all of this electrical activity. And these button electrodes will send the command to the unit to tell it when it should or should not deliver a shock.

There is a secondary sensing component here that's done across the two patches, and that's called PDF. It is a complicated physical principle, but basically the sensing leads here tell the defibrillator what is going on with the heart and they continuously monitor the heart's activity and send the message to the defibrillator when to deliver the shock.

Q And how is the shock delivered? Across what and what happens when the shock comes?

A Okay. When the message comes from these two leads here to the defibrillator and all the systems are go and the defibrillator is to deliver a shock, it will charge its capacitors inside here. This is similar to a flash on a camera being charged. The batteries are there, but they don't hold the charge all the time. You have to actually press the button and have the flash charge.

When that charge is peaked, then it delivers a shock across these two patches. The shock spreads across the internal screen on the patches and, therefore, the energy goes across the two patches here.

Q And what happens to the heart when the shock is delivered?

A The heart is suddenly what we call depolarized and that's

[Luceri — page 139]

Q Prior to the time you became involved with CPI when it commenced manufacture of the automatic implantable cardioverter defibrillator, you were practicing in Florida; correct?

A Correct.

Q Had you much, if any, experience with CPI as a company before that time?

A No. I had virtually no contact with CPI prior to that time.

Q And so the automatic implantable cardioverter defibrillator was really CPI's introduction to you?

A For the most part, yes.

Q And did you then come to become more familiar with CPI as a company?

A Yes, that's correct.

Q Did the introduction of the automatic implantable cardioverter defibrillator to you have any affect in terms of your dealings with CPI?

A I'm not sure I understand what you mean by "dealings."

Q Probably I didn't phrase it very well.

Did you, after becoming involved with CPI's automatic [Luceri - page 140] implant cardioverter defibrillator also learn about CPI as a company and its other products?

A Yes, that's correct.

Q And had CPI had much of a presence in terms of its ability to market product down in your part of the country before this product came around?

A Not to my knowledge, no.

Q And what effect, from your point of view in that area of the country, did the automatic implantable defibrillator have in terms of CPI's ability to market its other products?

A I think from a marketing point of view, it gave them an introduction into that part of the country.

[Luceri — page 141]

every instance where someone has a ventricular tachycardia, they die as a result of that episode?

A No, not in every instance.

Q Are there different types of ventricular tachycardia?

A Yes.

Q Are some lower rate* that is, the heart is not going as fast as other types?

A That's correct.

Q Are there some types of ventricular tachycardia that are more stable than others?

A Yes.

Q That is, that are less life threatening?

A That's correct, yes.

Q Do they tend to be lower rate tachycardias?

A Slower, yes, they are slower.

Q They are slower?

A Mm-hmm.

Q And could you give me an example of the slow rate tachycardia?

A An example would be let's say approximately 110, 110 beats per minute, usually, depending upon the status of the heart itself. That rate can't be tolerated until the patient gets to medical attention. Of course, as I said, it all depends on the status of the heart. If the heart is very weak to start with, then even at rates as low as 110 beats per minute, which is [Luceri — page 142] within an otherwise normal exercise rate, that heart will tolerate very poorly. So if we have a more — a healthier heart, that can tolerate faster rates.

Q So for hearts that are beating 110 to 120 beats per minute, it could either be an abnormal fast heartbeat or it could be the result of normal exercise; is that right?

A Not ventricular tachycardia.

Q But just in terms of heart rate?

A In terms of rate, yes, that's correct.

Q Now, does the Intec or CPI defibrillator treat tachycardias or fast heart rates in the 110 to 120 beat range?

A No, generally not. No.

Q Are drugs sometimes given to patients who use the CPI defibrillator in order to speed up the rates of tachycardias?

A Ventricular tachycardias?

Q Yes.

A No, not to my knowledge.

Q Not to improve the sensing?

A No.

Q Now, I would like to make it clear exactly which leads were functioning that you referred to in connection with these charts. I will direct you to Exhibit 632E and direct you in particular to the lead which goes down into the right ventricle. Do you see that?

A Yes.

[Luceri — page 156]

mandatory in the protocol. They were up to the investigators

Q And the FDA knew that and was part of the protocol that had options in it?

A Yes.

Q And do you know whether there is an option in the Medtronic protocol as to whether or not to use a third patch?

A I believe there is, but -

Q You don't know.

A I don't know for sure, no.

Q Now, you testified about the quality of life of people who receive Lilly defibrillators and I'd like to direct your attention to a study that you did on the quality of life. Do you recall that study?

A Yes, I do.

Q And in that study you looked into the effects of patients who had received these defibrillators and how they - how their quality of life was after they had gotten them; is that right?

A That's correct.

Q And in that study didn't you find that about 85 percent of the patients who had gotten shocked by the defibrillator described later to you that they had what I think you called significant fear?

A Yes. They were afraid, yes.

Q And wasn't the fear of shocks one of the factors that you associated with reduced physical activity in about 65 percent [Luceri - page 157] of the people who had gotten these defibrillators?

A Yes.

Q And did you find that there was a reduction in the social interactions of these defibrillator recipients, at least in about 41 percent of the time?

A Yes, there were.

Q Did you find that sexual abstinence was reported by about 41 percent of this group?

A Yes. I believe that's the figure.

Q And did this lead you to conclude that the automatic implantable defibrillator is associated with multiple physical, social and psychological alterations?

A Yes.

Q Now, you have also reported on a technical side, I think, between interactions between the defibrillator and pacemakers in those devices where both of them are used?

A That's correct.

Q Maybe I should start, to be sure we understand each other, there is no pacemaking function that's in the defibrillator itself, is there?

A Correct.

Q So for the patients who need a pacemaker, they have to get a separate one in addition to the defibrillator?

A That's right.

Q Is that done - that's a separate expense, I assume?

[Luceri - page 158]

A Yes.

Q Is it a separate operation?

A Yes. It is two different areas of the body.

Q Now, are there sometimes interactions between the defibrillator and the pacemaker?

A Yes, there may be.

Q And is it possible in your experience that the defibrillator can ignore a fast heartbeat because it was actually listening to the pacer instead of the heart?

A Yes. That's correct.

Q And in that circumstance, it could fail to deliver a shock because it thought everything was all right?

A Yes.

Q And in your experience, it is possible that there could be what's known as double counting and which I understand - correct me if I am wrong - means that the defibrillator has to listen to both the heart and to the pacer, so that it counted more beats than actually occurred?

A Yes. That's stretching it a little bit, but there is —

Q I am trying to phrase it so the jury will be able to understand.

A Yes. That's correct. There may be double counting.

Q And when there is double counting, can that lead to unnecessary shocks to the patient?

A Yes.

[Luceri — page 159]

Q Because the defibrillator thinks that the heart is fibrillating and it really isn't?

A Correct.

Q Is this more of a problem when you use dual-chambered pacing?

A Yes, it is.

Q Even when the dual-chambered pacing is at relatively low rates?

A It may be. We've gotten around that by using bipolar dual-chamber pacemakers.

Q And that helps somewhat?

A That helps a lot.

Q Now, in addition to these problems, are there various complications and device failures which are known to occur with the Lilly defibrillators?

A Absolutely.

Q And do they include post operative heart failure, coronary artery erosion, subclavian thrombosis, postoperative stroke, pneumonia, pleural effusions and infections of the generator site.

[Luceri — page 166]

defibrillator can't be used with these tachycardias in the 110 to 120 beat range?

A It could if it had programmable rate. In other words, you can have a CPI defibrillator custom made so that the rate cutoff is below the rate you desire, such as 110 or 120. That's not the problem. The essential point here is the programmability.

You have a choice — you don't have a choice, you have one rate that comes with that particular defibrillator and since the usual rate is over 155 and most defibrillators are made — are manufactured with that as the cutoff rate.

Q And if you had one that was made to detect 110 beats, what would happen if you went out jogging?

A You may trigger inappropriate shocks if the heart rate while jogging was more than 110 beats, unless there was a more sophisticated sensing circuit.

Q Is 110 a heart rate that someone in my poor condition could raise if I went out jogging?

A Sure.

Q Now, the CPI defibrillator doesn't have any way to give sequences of pacing pulses, does it?

A That's correct.

Q So it doesn't have any way of trying to slow down the pacing of a fast heartbeat?

A That's correct.

[Luceri — page 167]

Q And it can't deliver, for example, a burst of pacing pulses, can it?

A No, it cannot.

Q And it therefore doesn't use its defibrillation energy just as a back-up for some other therapy, does it?

A No.

Q Now, isn't it true that all of these features we have just discussed you have said should be in, and I will quote you, the ideal implantable device?

A Absolutely.

MR. JOHNSON: Thank you. I have no more questions.

REDIRECT EXAMINATION

BY MR. MALLOY:

Q Doctor, does the CPI automatic implantable cardioverter defibrillator continuously or continually monitor the functions of the heart?

A Yes, it does.

Q Is that your view even though — let me ask you this:

Are there periods of time in the device when it doesn't sense, does not sense during the charging of the output capacity?

A Yes. Technically speaking, there are brief periods of time where the device does not sense. You mentioned one, when it is charging the capacitors. Another is the, what we call blanking period that occurs around the time of sensing of the QRS or

DAY 7 TRIAL TESTIMONY OF DR. ROBERT HAUSER [page 20]

BY MR. MALLOY:

Q What effect, if any, has the VENTAK automatic implantable cardioverter defibrillator had on CPI as a company?

A It has had an enormous effect. Prior to the acquisition of the AICD technology, CPI was a dying company. Its products were not on the leading edge. It was difficult for physicians to even be accessed by CPI to demonstrate the products.

With the AICD, we have attracted additional talent, engineers, clinicians, managers, technicians, nurses, everyone now is very excited about this technology and it has literally turned the company around.

We not have ready access to physicians, electrophysiologists, cardiovascular surgeons. I think it is best described by one of our long-term employees who has been with CPI since the mid 1970's. He told me that prior to the AICD, it was difficult to get physicians to answer his calls. Now he has greater access to those physicians. So it has substantially helped CPI as a company.

Q Tell us what an electrophysiologist is.

A An electrophysiologist is usually a cardiologist, but may be a cardiovascular surgeon who specializes in abnormal rhythms of the heart.

Q Has CPI done anything to help the nation's — United States' electrophysiologists in terms of treatment of [Hauser — page 21] ventricular tachycardia and ventricular fibrillation?

A Well, I think our principal contribution has been in the training of these physicians in the AICD technology. We have trained over 200 centers in the United States who are now implanting the AICD and this includes physicians and surgeons from these centers who attend a two-day course in St. Paul at CPI headquarters. This course is conducted by a faculty which includes physicians, guest speakers from Johns Hopkins, for example, or Stanford, and also the faculty includes engineers and technicians from CPI.

Q Tell us in your view what the relative significance or lack of significance of Dr. Mirowski and his invention of the automatic implantable cardioverter defibrillator is.

A Well, if you simply reflect on the facts, the fact is that we are treating a group of patients who are going to die in a fairly short period of time. With the AICD, the clinical data, the clinical information, the clinical results already show that these patients have a 95 to 98 percent chance of survival.

If you then project that onto the number of patients at risk in this country, one might anticipate that over the next 10 years the AICD will save over a half million lives, and that's equivalent to the population of Minneapolis, St. Paul. That falls into a class

of treatment, a quality of treatment, that compares favorably with insulin, with penicillin, and with cardiac pacemaker?

[Hauser — page 22]

I believe that 10 or 15 years from now medical students will be reading about Dr. Mirowski's contribution. I believe that 10 or 15 years from now, I will be telling my grandchildren or —

MR. JOHNSON: Objection. Irrelevant.

THE COURT: No. Overruled.

THE WITNESS: I believe I will be proud of what we are doing with the AICD.

I also believe that some day Dr. Mirowski will receive the Noble [sic] Prize of medicine.

MR. MALLOY: No further questions.

[Hauser — page 42]

Q Pacemakers are intended to treat either no heartbeat or slow heartbeat; is that right?

A The majority of pacemakers are used to treat no heartbeat or a slow heartbeat. There are pacemakers that are used to treat rapid heartbeats.

Q When a pacemaker is used to treat slow heartbeat or no heartbeat, that's called a bradycardia therapy?

A That's correct.

Q And it is well known, isn't it, that after you defibrillate the human heart, that bradycardia often is the result, at least for a period of time?

A That's not true.

Q You haven't experienced a lowered heartbeat after a defibrillation with your patients?

A In some patients that can occur, but it has been the report of groups such as Dr. Aker's group in Milwaukee that slow heartbeats are infrequently observed after defibrillation.

Q Now, normally when you defibrillate a heart, it starts beating again by itself, doesn't it?

A Yes.

Q Now, occasionally it doesn't start beating again by itself; isn't that right?

A Occasionally.

Q And is that called asystolen?

A Or bradycardia.

[Hauser — page 43]

Q Or bradycardia?

A Yes.

Q And if a pacemaker happens to be implanted in that patient or in the case where the device could function as one, the provision of that small stimulus would get the heart going again, wouldn't it, in most instances?

A In many cases, yes.

Q This had led you to suggest that it would be a good idea to add pacing to an implantable defibrillator, hasn't it?

A I don't know what you are referring to.

Q Have you ever suggested it would be a good idea to add pacing to an implantable defibrillator?

A Yes.

Q Dr. Mirowski and the people he has been working with have been saying that pacing would be available in the Intec CPI defibrillator shortly for quite awhile now, haven't they?

A I don't know that.

Q Do you recall attending a symposium where you were the reporter in 1984 where Dr. Mirowski spoke on that topic?

A I have attended many, many meetings, as you know from my curriculum, and perhaps you could refresh my memory.

Q Do you recall going to a symposium which you later reported the panel from entitled The Role of Devices in the Control of tachyarrhythmias?

A Was that published in Pace?

[Hauser — page 44]

Q Yes.

A Would you mind showing me the document?

MR. MALLOY: I think that would help us, Mr. Johnson.

MR. JOHNSON: I will be happy to show the doctor the document.

THE WITNESS: Yes. This was the report of a panel meeting at the National Institute of Health where I was the reporter for the NIH.

BY MR. JOHNSON:

Q You prepared this document then?

A Yes.

Q And did you report that Dr. Mirowski said that within a few months, we will have pacing capabilities as well? That's the underlined portion there?

A Yes.

Q And that was back in 1984?

A Yes.

Q And you don't have pacing capabilities yet with any commercially approved device, do you?

A No.

Q Are there patients with tachyarrhythmias now who are not good candidates for the CPI defibrillator?

A Patients with atrial tachyarrhythmias are not candidates for the device. Patients who do not have critical rapid heartbeats are not candidates for the device.

DAY 16 TRIAL TESTIMONY
OF DR. ROBERT HAUSER

[page 35]

BY MR. MALLOY:

Q Doctor, in your direct testimony during our case in chief you testified a little bit about therapy acceptance. I want to ask you a couple questions abouts CPI's present plans for training as they relate to therapy acceptance, and simply as a background so that we have a context, would you tell me what you mean by therapy acceptance with respect to the automatic implantable cardioverter defibrillator.

A Yes. Therapy acceptance is a phrase that we have used and others have used to describe the understanding and application of any treatment which may include a drug, surgery or device, and typically, as a new therapy is introduced, and the information is disseminated in the medical community, there is some acceptance curve that one can describe based on the utilization of that therapy. One can accelerate acceptance by improving the dissemination of information to the medical community.

Q Is there any question of the strength or fragility of therapy acceptance as it relates specifically to the automatic implantable cardioverter defibrillator?

A I think with any new therapy it is important to introduce it in a very systematic fashion based on solid scientific evidence.

Q Is it possible in your view that a device in this very same

[Hauser — page 36]

field introduced but with defects and which doesn't work properly could have an effect on that therapy acceptance?

A Unquestionably.

Q Now, what, if anything, is CPI doing in terms of its present plans to train cardiologists or electrophysiologists if that has any bearing at all on therapy acceptance?

A Well, we simply want to insure that the device is properly applied, we are doing so, as I mentioned during my original

testimony, by conducting seminars at CPI, which include some experience in the pre-clinical laboratory. Next week, for example, at the American College of Cardiology, we will have a symposium and AICD therapy, which will include cardiologists, electrophysiologists and other physicians potentially.

This year we plan to conduct additional programs for positions all around the world. They will either be at CPI or at Satellite Symposia. We actually plan over 100 such meetings during 1988.

Q And the meetings are to train whom with what?

A They are intended to familiarize physicians who may not implant the device with the benefits and the proper indications for the device. They are intended to train physicians specifically as some programs are designed to acquaint physicians with the technical characteristics of the device, the implantations techniques and the follow-up care of these patients.

**DAY 7 TRIAL TESTIMONY OF
MICHAEL KALLOK
[page 78]**

"BY MR. MALLOY:

Q Has it ever been suggested by anyone to your knowledge at Medtronic that the first unit of the 7215 should not be implanted in the United States?

A Yes, I believe that's been suggested.

Q By whom?

A I don't know that I remember the individual.

Q What reasons, if any, were given for the expression that the first unit of Model 7215 should not be implanted in the United States?

A The reason I am aware of is that it was possible to implant a unit in Canada prior to approval by the FDA to implant a unit in the United States.

Q To date where have all units of the Model 7215 been manufactured?

A At Medtronic's facility in Fridley —

Q Minnesota?

A — to the best of my knowledge. Yes. The final assembly of those units did not occur at Medtronic's facility in Fridley, Minnesota.

Q Why not?

A The final assembly occurred at Medtronic's facility in Canada.

Q Why?

A The FDA does not permit a device that is not approved for

[Kallok — page 79]

clinical trials to be exported from the U.S. However, subassemblies of those devices can be exported from the U.S.

Q Were all components necessary for the final assembly of the 7215 which is to be delivered to Dr. Klein completed in the United States, to the best of your knowledge and belief?

A Yes, to the best of my knowledge and belief, all the subassemblies required for Model 7215 for the units that either have been or will be delivered to Dr. Klein were manufactured in the United States."

MR. MALLOY: To page 330.

"BY MR. MALLOY:

Q So you expect to have a 7215 unit implanted in a human before any application for approval is filed with the FDA in the United States; is that correct?

A Yes."

**DAY 7 TRIAL TESTIMONY OF
JOHN KEIMEL
[page 144]**

Q Would you explain why?

A Well, we are currently spending quite a lot of money each year in design and development of the 7215 and before that the 7210. The current fiscal year that ends in May, for example, will find us approximately five and a half million dollars down. Previous years our spending has been approximately the same, about four to \$5 million per year over the last five or six years. And over that period of time, we have sold very few, relatively speaking, numbers of 7210 and 7215 devices, and I would be confused as to how we could be profitable in that respect.

Q Have you operated at a loss for that project?

A Yes. As I mentioned, this year we are operating at a loss of five and half million dollars, this fiscal year.

Q Mr. Keimel, continuing on with the PCD, 7215, would you please give us an overview technical description of how that device works. And if there are any demonstrative exhibits that you know of that we have here that you would like to ask for, would you please do so.

A Okay. That's the PCD 7215?

Q Yes. I would first like an overview technical description.

A Yes. It is a very complicated device and often times I don't know where to start.

Let me start off, then, by talking about the tachyarrhythmia control features of the device. In summary, it

**DAY 9 TRIAL TESTIMONY OF
DR. GEORGE KLEIN
[page 30]**

Mr. Johnson?

MR. JOHNSON: The defendant calls Dr. George Joseph Klein to the stand.

... GEORGE J. KLEIN, sworn ...

DIRECT EXAMINATION

BY MR. JOHNSON:

Q Dr. Klein, please tell the jury where you reside?

A London Ontario, Canada.

Q What is your current occupation?

A I am a cardiologist.

Q I am going to show you a copy of Trial Exhibit 1216. What is Exhibit 1216?

A It is my curriculum vitae.

Q Does it describe your accomplishments and awards and education accurately?

A Yes, it does.

Q Please describe your education after high school.

A I went to the University of Toronto, where I did an undergraduate degree. I graduated medicine in 1972. I did a residency training in internal medicine and cardiology at the University of Toronto between 1972 and 1977.

Between 1977 and 1979, I was a fellow in cardiology at Duke University in Durham, North Carolina. I then returned to University of Western Ontario in Canada on faculty in a division of cardiology.

[Klein — page 31]

Q Have you passed any specialty examinations?

A I passed the examination of the Royal College of Physicians and Surgeons of Canada in internal medicine and in cardiology and I am board certified in internal medicine and cardiology in the United States and I am a fellow of the American College of Cardiology.

Q Have you authored or co-authored any publications?

A Yes, I have.

Q How many and in what general subject matter areas?

A The publications are in the area of cardiac arrhythmias and techniques to terminate cardiac arrhythmias, and there are approximately 130 publications.

Q Have you additionally authored any abstracts?

A Yes. About the same number of abstracts.

Q And what is your current position again?

A I am an associate professor of medicine at the University of Western Ontario and I direct the arrhythmia laboratory at the university hospital.

Q Now, are you authorized by any government agencies to conduct clinical investigations?

A I am authorized by the Health Protection Branch in Canada and the FDA in the United States to conduct clinical — selected clinical trials.

Q Are you an authorized clinical investigator to implant the Medtronic Model 7215 device?

[Klein — page 32]

A Yes, I am.

Q Are you also authorized to implant the Intec CPI defibrillator?

A Yes, I am.

Q And have you in fact implanted either or both of those devices?

A Yes. We have implanted approximately 30 of the CPI devices and four of the Medtronic devices.

Q Do you know of any other physicians whose patients have received both the Medtronic, that is not the same patients, but whose patient population has received both the Medtronic Model 7215 and the CPI defibrillator?

A No. To the best of my knowledge, we are the only ones who have implanted both devices and had experience with both of them.

Q Were the Model 7215 units commercial units?

A No, they were not. They were implanted under an investigational or research protocol for compassionate use in patients who did not appear to have a viable alternate therapy.

Q What restrictions were placed on you by the Canadian government in connection with those implantations?

A The guidelines were that currently available devices or alternate forms of treatment were not satisfactory as the experimental device.

Q In connection with the implant that you did in Canada and

[Klein — page 33]

the 7215, did you do them in accordance with an FDA protocol?

A Yes. All the implants were done under strict research guidelines under protocol.

Q Have you signed an agreement called an investigator's Agreement with the FDA agreeing to be bound by those protocols?

A Yes, I have.

Q Now, in addition to being a clinical investigator, do you perform any consulting for Medtronic or any other company?

A Yes, I do.

Q About what percentage of your income do you derive from consulting for Medtronic?

A Approximately five percent or less of my income.

Q What are some of the other companies that you consult for?

A I consult with pharmaceutical industries, Noah Pharmaceuticals and 3M Corporation.

Q What do you do for 3M?

A They have a division, drug division named Riker Pharmaceuticals and I consult with them on their product, their anti-arrhythmic product.

Q What are the principal therapies which are provided by the Model 7215?

A The 7215 is an arrhythmia control device that has several functions. It has the capability to maintain heart rate at an adequate rate in case the heart rate becomes too low. A conventional pacemaker we all know about, have known about for

[Klein — page 34]

many years, is merely a little device that provides electrical impulses to the heart to keep the heart rate at an acceptable constant level, much like a thermostat. So first of all, it is a pacemaker, it is a pacemaker, a conventional pacemaker for bradycardia in a conventional sense.

Secondly, the device is also capable of treating very fast heart rhythm disorders by a variety of ways. We have several ways of treating very fast rhythm disorders. These can cause symptoms of dizziness, passing out or even death. We have several ways of dealing with those. One of the ways is to actually accelerate the heart artificially faster than the actual rhythm rate that the patient has spontaneously, and fortunately for us that in many instances stops the arrhythmia and brings things back to normal. We call that overdrive pacing or anti-tachycardia pacing. That is a painless method of stopping a fast heart rhythm problem and often it is even inperceptive, it is not perceptible to the patients.

Finally, for rhythm disorder really gets out of hand, the heart is racing so fast that nothing else seems to be able to bring it back to normal, we can apply a stronger electrical shock to the whole heart that essentially shocks it back to a normal rhythm with a single higher energy shock, much like a little explosion, if you will. It is not really an explosion, but it convulses the heart back to normal with a single high energy shock and we call that cardioversion or defibrillation.

[Klein — page 35]

So the device essentially does three things. It prevents the heart rate from going too slow; it can prevent rapid heart rhythm disorders by so-called pacing techniques or techniques that accelerate the patient's heart rhythm to stop their arrhythmia; and finally, if necessary, it can provide a higher energy shock to shock the heart back to a normal rhythm with a higher energy output.

Q In addition to the overdrive pacing that you mentioned, are there other therapies for treating the fast heart beats?

A Yes, there are. There are various ways of overdrive pacing. For simplicity, I don't think they are important to us, but there are various means of manipulating the patient's own heart rhythm during a fast heart rhythm disorder to bring it back to normal by the use of a pacing device which allows us to manipulate the heart rate.

Q In the Model 7215, is there just one pacing therapy for a fast heartbeat or are there several? Could you describe what's available in the device?

A There are an infinite variety of pacing techniques that one can try to stop a patient's heart rhythm disorder and they can be graded.

One can try a relatively simple therapy at first, a simple program, if you will, to bring the patient's heartbeat back to normal using manipulation of the heart rate. One can then become more aggressive and make it more rapid and more

[Klein — page 36]

complicated. Finally, if all that fails, one can induce higher energy shocks. Not only can one induce higher energy shocks, but one can induce higher energy shocks at a graded level.

For example, one can try a small shock at first, a relatively small shock that may not be as painful to the patient, and then if that doesn't work, you can try a larger shock to the maximum output of the device. So it provides an infinite variety of therapies

that one can apply to tailor to a given patient's particular rhythm disorder.

Q Who selects the therapies and how are they selected?

A The therapies are selected by the cardiologist who implant the device and we bring the patient — after the device is implanted, we bring the patient back to our laboratory, we turn off their rapid heart rhythm disorder by using the device. The device can actually be programmed to control the heart rate, so we can turn on the patient's own rhythm disorder and by trial and error, determine which is the safest and most pain-free way of bringing about cessations of this abnormal heart rhythm disorder.

Q You mentioned that you have implanted some 30 CPI defibrillators?

A Yes.

Q Could you compare for us your experience with the Medtronic Model 7215 and the CPI defibrillators, pointing out the advantages,

disadvantages and differences between the two units [Klein — page 37] from the physician's or patient's standpoints.

THE COURT: Well, may I see you.

(Whereupon, a discussion was held at sidebar on the record as follows:)

THE COURT: First of all, this sounds to me as though we are going to be comparing which is a better of the two devices, which I really don't think has any part of this trial, as I told Mr. Malloy on a couple of occasions.

MR. MALLOY: I agree, Your Honor.

THE COURT: Secondly, this sounds like it might be the sort of thing that comes within the public interest testimony that we talked about and it is for me rather than the jury. I just don't understand —

MR. MALLOY: I agree.

THE COURT: — why we want to compare the two devices. If we are saying this device is better or this is not as good —

MR. JOHNSON: Well, Your Honor, first of all, there has been a great deal of commercial success and these devices have been touted, and in fact I recall that Mr. Malloy's witnesses had direct comparisons which I complained about and he said no, they were appropriate to compare the two and in fact the testimony proceeded.

We have had direct comparisons before the jury in exactly the same issue.

[Klein — page 42]

MR. JOHNSON: Well, burst pacing is a tachycardia treatment.

MR. MALLOY: It is irrelevant.

MR. JOHNSON: It is absolutely relevant because they have alleged that they can come in and treat all this tachycardia and they can do great job and do it by delivering a whopping shock to people sometimes when they don't need it and I think the jury has every right to hear in its response to all these allegations of this great invention and how man kind has been helped by this. They have a right to see how this device works by comparison to what the CPI does. I think they ought to know and see how crude the CPI device is when it comes to treating tachycardia and what the effect is on the patients.

MR. MALLOY: Totally irrelevant, Your Honor. If they want to talk about their cardioversion and defibrillation with shock treatment, that's one thing.

THE COURT: No. I will overrule your objection, Mr. Malloy

(End of sidebar discussion.)

BY MR. JOHNSON:

Q Dr. Klein, I am going to repeat that question.

Without reference to the bradycardia pacing therapies that are provided by the 7215, would you please compare your experiences with the Model 7215 PCD and the Lilly CPI defi-

brillator as it relates to tachycardia therapies and [Klein — page 43] defibrillation therapies the two units provide, giving the advantages and disadvantages of each.

A Well, it is a little hard to compare them directly because actually the patients that we select for one are different than the patients that we have selected for the other. The older device, the older defibrillating device provided a shock to bring back heart rhythm disorder for a catastrophically fast arrhythmia. So the heart would start to race very, very quickly, the device would detect it and deliver a strong shock to the heart to bring it back to normal.

We have used that device in patients who are prone to develop these very rapid heart rhythm disorders, essentially ventricular fibrillation, that cause them to have symptoms very quickly, to have lightheadedness and to lose consciousness very quickly. This device will then shock them and bring the heart rhythm back to normal, and in summary, in that type of patient, our experience with the CPI device has been good in that it has fulfilled that function in a reliable way.

Now, however, we must remember that this device is essentially a one-trick pony. All it does is it shocks the heart back to normal. No matter what the fast rhythm disorder is, it is one answer to that, is a strong shock, which in a patient who is awake during the shock, if a patient doesn't pass out prior to the shock, the shock can be quite a traumatic experience, which varies from patient to patient, but some of [Klein — page 44] them find it very, very distressing. So it provides one therapy.

Now, there are another group of patients who will get very rapid heart rhythm disorders, but they are not quite as immediately dangerous as the group I have just described. They will get a very rapid heartbeating, but they won't pass out right away. Their blood pressure might drop a little and they may get a little lightheaded, but in general they will be able to tolerate their symptoms for a longer period of time and they are not in imminent danger of dying.

Now, this is that group of patients that we have selected for this other device, because for that group of patients, it is

really unacceptable to shock them each time they have one of these more moderate rapid heart rhythm disorders.

Q Excuse me. When you say the other device, would you tell the jury — be sure the jury knows which device you are talking about.

A I am sorry. For the group of patients that we have selected for the new Medtronic device, we felt that the CPI device was inappropriate, and the reason for that was that they developed frequent episodes of fast heart rhythm disorder that did not cause them to lose consciousness. Their hearts would race, they would feel bad, maybe a little lightheaded, but they could tolerate their fast heart rhythm disorder for a long time [Klein — page 45] without passing out or losing consciousness.

Now, for that group of patients, it would be almost unacceptable to have them shocked with a vigorous shock every time they got their rapid heart rhythm disorder. So for them we selected the newer Medtronic device which at first attempts to stop [sic] these rapid heart rhythm disorders with the more painless pacing techniques. That is — at first will try to accelerate the heartbeat beyond the patient's own heartbeat, in order to stop these rhythm disorders painlessly, and we can program this particular device to various therapies, as I explained before. We can try these pacing techniques, we can try a lower energy shock which might be less painful than a higher energy shock and only if all else fails does the new device resort to a more distressing high energy shock to stop the arrhythmia.

Q Doctor, is there any difference in the power levels that are inherently used and/or the safety relating to those levels between these two devices?

A The maximum output of the older CPI device is in the range of 30 joules, which is our unit of energy. The maximum output for the 7215 Medtronic in your device is in the range of 15 joules, so the max number energy for the newer device is approximately half of the older device.

How does this relate to safety? I think I can answer that

by describing how we decide when we put these products in

[Klein — page 46]

whether the energy is sufficient and the way we decide is on the operating room table with the heart beating and exposed, we make the heart fibrillate; in other words, using an electrical current, we make it race so quickly that it doesn't pump, it is in ventricular fibrillation.

We then, with the system that we are using, be it the older CPI device or the newer device, we then try to shock it back to normal using various grades of energy starting low and working our way up. The lowest energy that appears to consistently work we call the threshold energy.

So for the sake or argument in a given patient, we will try out one of the devices and find that we can consistently bring the heart back to normal with let's say five joules. If we then decide that our product has 15 joules, we then say that our margin of safety is at least threefold and that that device in that particular patient is acceptable.

If on the other hand, we find that we cannot defibrillate the heart unless we use 25 joules, then obviously that device is not acceptable for that particular patient. So the absolute energy of the device is not nearly as important as our so-called margin of safety.

For instance, if you can defibrillate with one joule, a unit of one joule, then there is not much point in putting a 30-joule device in, a 15 joule device is already sufficient overkill. It is like putting 100 horsepower into a lawnmower **[Klein — page 47]** when two horsepower will mow the lawn. So the margin of safety is more important than the actual energy output.

We prefer to use smaller energy devices if possible as a matter of choice because the size of the device is directly related to the battery. You may well say well, why don't we put in 200 joules in everybody. The higher the energy, the bigger the batteries that are required to power the device. The converse is true. The lower the energy that we can get away with, the smaller the battery and the more aesthetic the device, the more appealing

and the more easily one can implant it under a patient's skin. Ultimately we have to remember that this device has to go under a patient's skin and the bigger and bulkier the device, the less acceptable it is, especially to thinner patients and smaller patients.

Q Dr. Klein, are there any cost issues relating to the use of either of these devices?

A To the best of my knowledge, the cost of the two devices is comparable. They are both expensive.

Q Are these devices ever implanted along with other devices; that is, not just used alone?

A The older device —

MR. MALLOY: Your Honor, objection. I think we are getting into the territory that we talked about before.

THE COURT: Why don't you talk it over between yourselves and see if you can agree?

[Klein — page 49]

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. JOHNSON: Your Honor, I was about to ask the witness to describe the problems which result from pacemaker cardioverter interactions when the Lilly device is used with a separate pacemaker. We have had some testimony on this from I think it was either Dr. Luceri, I think it was Dr. Luceri and it is a significant disadvantage because of the problems which result from having shocks applied to patients when they shouldn't be applied or perhaps even missing events, that is missing things that ought to be treated which aren't treated.

MR. MALLOY: That's pacemaker. It is not relevant.

MR. JOHNSON: Well, I think it is directly relevant and it certainly is relevant to the patients, the ones who aren't getting treated or who are getting treated, and I think this is another aspect and they also, in this case, now are saying pacemakers are irrelevant, but if you will recall on the damage case, they

made a great deal out of the fact that this had turned around their business and their pacemaking business in going crazy and that this was part of the damage thing and I don't see why this isn't a perfectly appropriate inquiry, because it is a very real part of the way the device is used.

MR. MALLOY: It is totally irrelevant.

THE COURT: What fact does it go to prove it is an issue, Mr. Johnson?

[Klein — page 50]

MR. JOHNSON: It goes to show that the commercial — first of all, the damages side, that the commercial success that they are getting may come from use of pacers, but I think more importantly, it goes —

MR. MALLOY: Commercial success of whom?

MR. JOHNSON: Of CPI. We are talking about the separate pacing units which would have to be implanted.

MR. MALLOY: You just turned yourself upside down.

MR. JOHNSON: No. We are talking about that, but I am also talking about the fact that the Lilly defibrillator once again does not have the ability to reliably treat patients who also need separate pacing units. The reason is because it applies shocks which are inappropriate because it is listening to the pacer instead of listening to the patient or it shock applies shocks which are inappropriate because it is listening to both the patient's heart and the pacer or because it is listening to the pacer and not listening to the patient's heart, it thinks everything is okay when in fact the patient could be in fibrillation.

This is a critical part, a critical piece of evidence to rebut their commercial success, the long felt want. It gives a basis for the reasons of skepticism expressed by others that they have relied on to try to prove unobviousness of the invention. All of this is rebuttal to what they have presented.

[Klein — page 51]

THE COURT: All right. I will permit it.

(End of sidebar discussion.)

BY MR. JOHNSON:

Q Dr. Klein, are the Lilly or CPI defibrillators sometimes implanted together with other devices?

A Yes, they are. They are often implanted together with ordinary pacemakers. As I mentioned, sometimes ordinary pacemakers are required to keep the heart rate from going too slow. They are also sometimes implanted with so-called anti-tachycardia pacemakers or that is the special pacing that I described which will accelerate the patient's own heart rate above the heart rate of the rhythm disorder in order to stop it painlessly.

So that in point of fact, the functions of the new device, the Medtronic 7215, are all there and other devices are not necessary with it, but with the older device, as I said, since it is only a shocking device, will also occasionally need another pacemaker to — for slow heart rhythm disorders or a specialized pacemaker to stop very rapid disorders, all of which are included in the new device in itself.

Q Dr. Klein, are there disadvantages in using multiple devices in the same patient, that is, the Lilly defibrillator along with these other types of pacemakers you have mentioned?

A Well, I would say yes, there are disadvantages. The first disadvantage is the cost, the cost of having two expensive [Klein — page 52] devices rather than just one expensive device.

The other problem is that at this point, the two devices were not made with compatibility, particularly in mind, so that one has problems with the function of one device perhaps interfering with the function of the other device.

Q How do those functions interfere, if they do?

A Well, one possible cause of interference is that —

MR. MALLOY: I am going to object to "possible," Your Honor. I don't know if we are testifying about fact or opinion here.

THE COURT: Well, I will let Dr. Klein describe the interferences that he has observed.

I don't think we are interested in remote possibilities, but I will certainly permit you to describe the ones that you observed yourself, Dr. Klein.

THE WITNESS: Since we have not implanted the two together, I can't comment on my personal experience. If I may rephrase that to say —

MR. MALLOY: Your Honor, I object to continuing comments of the witness, and I don't mean to interrupt—

THE COURT: Let me hear what he is going to say.

MR. MALLOY: Okay.

THE COURT: How are you going to phrase it, Dr. Klein?

THE WITNESS: How about an interaction that has been observed in the literature between the two devices?

[Klein — page 53]

MR. MALLOY: Well, Your Honor, this goes beyond what we had and I think he is here to testify about his own experience.

MR. JOHNSON: Your Honor, he is an expert and the other experts have testified throughout the trial based on their knowledge of the literature.

THE COURT: No, I will permit it.

THE WITNESS: An ordinary pacemaker or pacing device puts out electrical impulses. These electrical impulses can be — can fool the other device into thinking that the heart rate is racing faster than it actually is going, so one device is there pacing the heart, but yet the other device cannot distinguish between that device pacing or artificially [sic] stimulating and the patient's own intrinsic heart rate. So it can be fooled into

delivering shocks inappropriately when in fact the patient's heart rate is not in a ventricular fibrillation.

BY MR. JOHNSON:

Q Are there any adverse or adverse psychological effects that you have observed from use of the Lilly or CPI defibrillator?

A We have observed adverse psychological effects with any device that uses high energy shock on a consistent basis. In one particular patient with the CPI device, we actually had to explant the unit and resort to cardiac transplantations because this patient became psychologically totally disabled by the

[Klein — page 54]

fear of getting shocks, which to him were very uncomfortable, so this patient would just sit in his room all day afraid to move for fear that this device would set off a shock in his chest, which caused a great pain to him.

So I think that it is very, very important in these patients to try to treat the patient with a painless therapy and only resort to the shocks if absolutely necessary, and I think everyone in this field agrees to the importance of trying to treat patients, if possible, with painless pacing therapies and resorting only to the more psychologically traumatic and painful shocks, if necessary.

Q I would like to direct your attention to the particular patients who have received the 7215 PCD. Would the CPI defibrillator have been a better choice for these patients?

A No. In the four patients that we chose, as I pointed out before, their problem was not this immediate catastrophic ventricular fibrillation that caused them to lose consciousness and for which they required an immediate shock. Their problem was a less pronounced tachycardia or fast heart rhythm disorder which did not cause them to lose consciousness. They felt bad, they had to go to the hospital to get it treated, but they were perfectly awake and alert. Some of them were experiencing their fast heart rhythm disorder once every two days, so to put the alternate device in would require a strong shock in the chest to them every second day, which would not only create [Klein — page 55]

psychological mayhem, but would also deplete the device in a very short time.

So in that particular patient in particular, it was very important to implant the device that would stop the rapid heartbeating disorder by alternate pacing techniques and resort to the shock only if absolutely necessary. And it is fair to say that all four patients fit those criteria of having rhythm disorders, although very serious, but having rhythm disorders that left them relatively alert and conscious during the therapies.

Q Could these patients have been adequately treated just with drugs?

A Aggressive drug trials with one or more drugs at a time failed to successfully control their rhythm disorders. They all had very serious cardiac problems.

Q What were the other available treatments for these patients besides the Medtronic Model 7215?

A The only realistic alternatives in our patients were heart transplantations or the use of the CPI device in conjunction with other sophisticated pacing devices. We don't like to do cardiac transplantations except as a last resort. The waiting lists for that are just horrendous, there are other problems, so that realistically our alternatives were between the 7215 and a CPI device in conjunction with another specialized sophisticated pacemaker. So we chose the newer device which [Klein — page 56] incorporated everything into the unit, the original unit.

Q What was the prognosis for these patients without the treatment that they received?

A The long-term outlook of these patients was not immediately that grim. In other words, they did not have a total cardiac arrest, as I explained, every time they got their fast heart rhythm disorder, but nonetheless, they were very disabled and they had to make frequent trips to the hospital. The last gentleman that got the 7215 had been in a hospital for approximately four months without being able to get out of the hospital, because of getting this problem every second day, so I think the prognosis for a relatively rehabilitated life in these patients was almost zero.

Q Are all of the patients who received the 7215 device still alive?

A No, they are not. One patient has died.

Q Did this death have something to do with the Model 7215?

MR. MALLOY: Maybe the other way around.

THE COURT: I am sorry?

MR. MALLOY: Maybe counsel meant to ask it the other way around.

MR. JOHNSON: I am sorry. I did mean to ask it the other way around.

BY MR. JOHNSON:

Q Did the Model 7215 have anything to do with this death?

[Klein — page 57]

MR. JOHNSON: Thank you, counsel.

THE WITNESS: No. I don't believe that the Model 7215 had anything to do with the death.

BY MR. JOHNSON:

Q Okay.

A If I may qualify that, as I am sure I will have to sooner or later, the device — the patient — this patient died. This patient had previous suicide attempts and was very psychologically disabled from his problem. In fact, several months before we put this device in, this patient was so despondent that he overdosed on two very toxic cardiactive medications, one of them being Digitalis and one of them being a drug called Sedalone (phonetic). The patient came to the emergency room close to death with low blood pressure and a very slow heart rate. At the time of this patient's actual death, he had toxic levels of the drug Digoxin in his body which were twice the upper limit of the acceptable level, so he had undoubtedly again overdosed. The mode of presentation the first time he overdosed was low blood pressure and slow heart rate, so I think that my best estimate of the cause of death was that the same thing happened.

When we talk about the device being implicated in death, we are talking about two potential ways it could be implicated. One potential way that a device can cause a death of a patient



is to go off inappropriately. So in other words, [Klein — page 58] when there is nothing wrong with the patient, this device can just go haywire and cause the patient's death by creating more problems and more mayhem than is present. That's one cause of death. That did not happen with the 7215 because we can interrogate the device, we can put a little receiver over the device and the device tells us the events, at least the cardiac heart rates at the time of any therapies and it also accurately records the therapies that it gave. So the device did not kill the patient. We know that because we can interrogate the device and the device did not go off to create any problems.

The second way a device can be implicated in the death of the patient is if the device fails to treat a therapy, fails to treat rather a rhythm disorder — for instance, in order to treat a rhythm disorder, these devices have to constantly sense the heart rate, so there is essentially a sensor there to tell it what the heart rate is. So if one says well, is it possible that this man had a rapid heart rate in which the sensor function of the device didn't work, I would have to say yes, that's certainly a possibility and that's always a possibility in any patient who has any of these devices.

Q Just so your testimony is clear, is it still your opinion then that the death was unrelated to the use by the patient in the 7215?

A That is my opinion and that was the official report as the cause of death. The official cause of death was written by the [Klein — page 59] pathologist involved in the case who was not related to our team, but the pathologist doing the case was a pathologist in Toronto. Our hospital is in London. The official cause of death cited by the pathologist at the other hospital was drug overdose.

Q How many of the remaining patients still have the Model 7215 PCD implanted?

A Two of the three remaining patients still have a Model 7215. One of the patients — I must point out that when a patient has heart problems, there are two general categories. One is the heart has to work as a pump, so in other words, it has to pump

blood to keep us breathing and to keep us from getting swelling and keep us moving around. The other function of the heart is electrical and that's to keep the rhythm in order. Any of these devices, at best, they just hope to keep the rhythm in order. In this particular patient, the device worked very well and kept the patient's heart rhythm in order and he did not get any abnormal heart rhythms that weren't treated.

On the other hand though, this patient had very bad heart disease and his heart as a pump had totally deteriorated in the interval between the time that we had implanted the device and the actual time of the transplant. So in other words, he had a progressive deterioration of his heart as a pump, so that at the time of the transplant, he was essentially [Klein — page 60] only running on half a cylinder, even though the electrical system was intact. So the reason for transplantation had nothing to do with the device, it had to do with the deterioration of the patient's heart as a pump.

The other two patients are doing very well. They are both using the painless treatments for their fast heart rhythm disorder quite frequently and they are not aware that their heart rates are going fast and being treated. And one of these patients is the one that had to sit in the hospital in Detroit for four months without being able to go home prior to getting this device.

Q Do you have other patients in your patient practice that could benefit from devices such as the Model 7215?

A Yes. We are a referral center for patients with arrhythmia problems and I would estimate that we would implant perhaps 50 of these devices every year if they were available to us readily.

MR. JOHNSON: Your Honor, I think we have reached the point here you—

THE COURT: All right. Members of the jury, this would be a good time for us to take a brief recess, so can we take about five or ten minutes, please.

(Jury out at 11:10 a.m.)

THE COURT: Let the record reflect that we have excused the jury, please.

[Klein — page 61]

BY MR. JOHNSON:

Q Dr. Klein, is there an ongoing need for devices such as Medtronic's Model 7215?

MR. MALLOY: Excuse me. I know the jury is absent, but if we could have non-leading questions, I still think that would be better.

BY MR. JOHNSON:

Q Dr. Klein, what is the need, if any, for the devices such as the Model 7215?

A I think the need for devices such as the Model 7215 is enormous. The CPI device, the original device really showed us the potential for treating patients with electrical devices and the advantages of this particular electrical device and newer generations is enormous. There are so many patients out there with serious heart rhythm disorders that require this therapy.

A few years ago we had a wave of enthusiasm for surgical treatment of these cardiac rhythm disorders, but unfortunately most of the patients who have this problem have such severe heart disease that the mortality — the survival of surgery is often exceedingly low. Many times the heart function is so badly compromised, so badly damaged that all our anti-arrhythmic drugs fail to help these patients, so that the development of sophisticated and very versatile devices to treat these problems is enormously important and I think that the more people that get into the fray to give people these [Klein — page 62] devices, the better off everybody will be.

Q Is there a public interest in having more than one company experiment in this area in your opinion?

A Well, I think that with the natural history of any product, once there is intense competition and many, many independent efforts to come up with better products, that's when we traditionally evolve cheap products, effective products and we develop innovative ideas and newer ways of dealing with old problems.

Q Is there any public interest in proceeding with experimental investigational studies of the type that you are working on?

A Well, I think it is enormously important to the public. The four patients that we used the Model 7215 in we felt that it was the only realistic available option to them, and there are many more patients out there other than the four that we have implanted. In fact, the investigators for this device have been complaining to get these devices for their patients and they have been limited by device availability.

MR. JOHNSON: Your Honor, I have no further direct examination.

MR. MALLOY: Could I cross him on this and then we will go back to the other?

THE COURT: Sure.

CROSS-EXAMINATION

[Klein — page 98]

Q Doctor, was there any implication of alcohol use with this particular patient Mr. Malloy has been asking you about?

A If I am not mistaken, an empty 40-ounce bottle of Southern Comfort was found at his bedside when he died, so we also — that alcohol was implicated in the cause of death of this patient.

BY MR. JOHNSON:

Q Was an alcohol level actually found at autopsy in the blood?

A I don't recall. I am sure that's in the record.

Q Don't you still have the letter in front of you?

A Oh.

Q Please look at D-11.

A D-11.

Q Pages D-11.

A 732?

MR. JOHNSON: Tim, did you take the letter back from the witness?

MR. MALLOY: Here, you are. No, I didn't but you are welcome to my copy.

THE WITNESS: Yes, I have it here. The alcohol level was 111 millimols and toxicity would be seven millimols per liter, so there was evidence of excessive alcohol, although it was not — it could not be considered high enough to be the cause of death by itself. It was high enough to be a [Klein — page 99] contributing factor.

BY MR. JOHNSON:

Q And what was the Digoxin level?

A The Digoxin level was 4.37 millimols per liter and the upper limit of normal is 2.56, so just about twice the upper limit of acceptable.

Q Was there any abnormal liver indicated that would be consistent with heavy drinking?

A The patient's liver was very —

MR. MALLOY: Your Honor, I am going to object. He has already indicated that it wasn't the cause, so I think we are belaboring —

THE COURT: No, I will permit it. Overruled.

THE WITNESS: The patient's liver was severely cirrhotic due to his long standing problem with alcohol and psychological problems. Cirrhotic means alcohol scarred.

BY MR. JOHNSON:

Q Now, I would like to direct your attention back to a few of the other matters that were raised by Mr. Malloy. He asked you, I think, could the Model 7215 be operated with sequential pulse or without sequential pulses. Does the protocol that you follow indicate how it is to be operated?

A I believe that the protocol is to use sequential pulse defibrillation.

Q And you followed the protocol?

[Klein — page 100]

A That's correct.

Q And does the protocol indicate the types of electrodes that you are to use?

A It does indicate the types of electrodes. We have some option as to size.

Q Are they always patch electrodes?

A They are patch electrodes.

Q And you have always followed those protocols, haven't you?

A Yes, we have.

Q Now, you referred to constantly sensing in your testimony on your cross-examination. Do you know what the device does when the capacitor charges in that regard?

A The capacitor charges, that means that the battery is getting ready to deliver a charge, so at that time the device, to the best of my ability — again, I am not an engineer — but to the best of my ability, while the battery is charging, there is so much electrical noise that it is almost impossible to be able to sense properly to detect properly, so during the time that the battery is actually charging, the monitoring functions of the device temporarily cease.

MR. JOHNSON: I have no further questions.

RE-CROSS-EXAMINATION

BY MR. MALLOY:

Q Doctor, isn't it the fact that you and others have experienced that sequential pulse has operated on many

[Klein — page 103]

Q By Medtronic?

A By Medtronic, that's correct.

MR. MALLOY: Thank you.

MR. JOHNSON: No further questions.

THE COURT: All right. Thank you, Doctor.

(Witness excused.)

MR. JOHNSON: Your Honor, our next presentation is a videotape deposition of Dr. Zacouto. We can start it now or we could take an earlier lunch and start it after lunch.

THE COURT: Well, this is one of those days when I can't come back until 2 o'clock, so at least if we can get it started, I think that may be helpful.

MR. MALLOY: Could we approach the bench, Your Honor, with a small point.

THE COURT: Certainly.

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. JOHNSON: Your Honor, I don't have any problem with this paragraph. This paragraph begins to get into an instruction which is far beyond the scope of what we are talking about. However, we start here in the second paragraph, two begins, "Whether the patents are valid or invalid depends on a comparison," and then I would suggest that the problem with this portion of the instruction is that it seems to suggest to the jury, this particularly alleged existence

**DAY 13 TRIAL TESTIMONY OF
JAMES VEALE
[page 35]**

... JAMES RANDALL VEALE, sworn ...

DIRECT EXAMINATION

BY MR. LEVIN:

Q Mr. Veale, would you please state your full name for the record?

A James Randall Veale.

Q What is your current profession?

A I am a consultant in the regulation of medical devices about Food and Drug Administration.

Q And where is your business located?

A In Attleboro, Massachusetts.

Q Could you tell us what degrees you received after high school?

A 1966 I received a bachelor's degree in electrical engineering.

THE COURT: Mr. Veale, try to keep you voice up. I want you to talk towards the jury but it would be helpful to me if you would talk good and loud because I am not going to be able to see your face.

THE WITNESS: I will certainly try. 1966 I received a bachelor's degree in electrical engineering and in 1972 I received a master's degree in electrical engineering.

BY MR. LEVIN:

Q Could you recount for us your professional career.

[Veale — page 36]

A After getting the bachelor's degree in electrical engineering in 1966, I was with the Air Force for four years as an electronics engineer.

In 1970 I left the Air Force as a captain, went back to graduate school and studied biomedical engineering and electrical engineering.

In 1973 I joined the Food and Drug Administration as a biomedical engineer as part of a staff that the Food and Drug Administration was assembling to help them set up regulations for the regulation of medical devices.

In 1977, while at the FDA, I was appointed a division director responsible for the review and approval of new medical devices that were being submitted to FDA for approval.

At the end of 1984, I left FDA and became a consultant and have been consulting in the regulation of medical devices and FDA's requirement for medical devices since.

Q As part of your work at FDA, were you involved in the review of IDE or PMA applications relating to medical devices?

A Yes, I was.

Q And approximately how many IDE applications did you personally review during your period with the FDA?

A While I was at FDA either I personally reviewed or I supervised the staff who reviewed several hundred IDE's. I don't remember the precise number.

Q Did any of those IDE applications concern implantable

[Veale — page 37]

medical devices?

A Yes. Yes, they did.

Q Do you recall approximately how many there were?

A Again, I don't know the precise number, but it would be at least 25 and probably as many as 50.

MR. MALLOY: One short point. May we approach the bench, Your Honor?

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. MALLOY: The thought just struck me, and it may be that this is not even going to be pertinent, but I think it would be inappropriate if he is going to testify as to any actual personal experience or supervisory contact with any of the applications that are involved in this case.

MR. LEVIN: He is not.

MR. MALLOY: Okay.

(End of sidebar discussion.)

BY MR. LEVIN:

Q During your period with the FDA, did you personally supervise the review of any PMA applications?

A Yes, I did.

Q And approximately how many PMA applications were there?

A Again, either I personally reviewed or I supervised a staff that reviewed probably 25 or 30 premarked approval applications.

[Veale — page 38]

Q And did any of those involve implantable medical devices?

A Yes. Quite a number did.

Q Could you tell us what kind of implantable medical devices?

A They were a wide variety of implantable devices, varying from such products as plastic implant to implantable neurostimulators, a type of pacemaker that's used for stimulating the nervous system.

Q I would like to show you what we have marked as Trial Exhibit 1215 and ask you whether that is a copy of your curriculum vitae?

A Yes, it is.

Q And have you published any papers regarding the regulation of medical devices by the FDA?

A Yes, I have.

Q Are those papers listed on your CV, Trial Exhibit 1215?

A Yes. This is correct.

Q Mr. Veale, in general, is the distribution of medical devices regulated in the United States?

A Yes. The distribution, sale and clinical application or clinical use of medical devices is regulated in the United States by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. That was amended in 1976 to extend extensive authorities over medical devices.

Q Now, are implantable cardioverters and defibrillators included within these kinds of regulating medical devices?

[Veale — page 39]

A Yes, absolutely. These devices, implanted cardioverters and defibrillators, are considered to be class three devices and are regulated the most — in the most strict fashion by FDA.

Q Can you give us a general overview of how the FDA regulates medical devices such as implantable cardioverters or defibrillators?

A Well, first these kind of devices, these lifesaving implantable devices have to be approved by FDA before they can be marketed. Even before they are approved for marketing, they are required by FDA to undergo fairly extensive clinical evaluation using human subjects. The experimental testing in human subjects itself has to be approved by FDA as well.

MR. MALLOY: Your Honor, I am going to object at this point as to whether or not the witness is testifying on his own personal involvement or simply as an after-the-fact expert and I think that ought to be brought out, because if it is personal involvement, I certainly have an objection.

MR. LEVIN: May we approach the bench, Your Honor? I thought we —

MR. MALLOY: I don't think it is —

THE COURT: Talk it over with each other.

(Whereupon, a discussion was held among counsel off the record.)

BY MR. LEVIN:

[Veale — page 40]

Q Mr. Veale, while you were with the FDA, were you personally involved in an IDE or PMA application relating to any implantable cardioverter or defibrillator by Eli Lilly, CPI or Intec?

A No, I wasn't.

MR. MALLOY: Or Medtronic.

BY MR. LEVIN:

Q Or Medtronic?

A No, I wasn't.

Q And during the period of your outside consultantship, which I believe you testified has been within the last year or so, have you been so involved?

A No.

Q I believe you testified that before a medical device can be sold in the United States, certain approvals are needed and before it can be tested in the United States, certain approvals are needed. Do these approvals have a specific designation within the FDA?

A The pre-market approval application is referred to by — as a PMA application. This application must be submitted to FDA after the device has been tested and before FDA will permit it to be marketed in the U.S.

Q What about the testing period that you referred to?

A During the testing period, that is during the period that is being evaluated in human subjects, the FDA requires that an

[Veale — page 41]

application referred to as an Investigational Device Exemption application or an IDE be submitted and approved by FDA. The IDE, when approved by FDA, limits the number of subjects and the number of hospitals or centers that the device can be implanted in and tested in.

Q Now, is there a particular application in which a company must make for an IDE?

A It is called an IDE application. It consists of information about the device, describing the design of the device and how it is built, the manufacturing information. It includes reports of all previous testing that was conducted on the device, that is all animal testing, laboratory testing and in some cases,

if it has been used in foreign countries, summary of the clinical uses in other countries.

It also includes a description of the investigational plan for the device, that is the procedures that will be followed in studying the device and the controls that will be taken to protect the patients during those trials.

Q And once an IDE issues, what happens?

A Well, once FDA approves the IDE application, then that gives the company the right to begin human trials or human testing of the device and they can proceed to do so. Typically, FDA will limit the number of subjects that can be — in this case, implanted with a device, and often the number of hospitals or centers that can take part in the study, but after [Veale — page 42] FDA approval of the IDE, then the company can proceed with the testing.

During the study typically the company will be required to report — submit progress reports to FDA as to how this study is going and they are allowed to proceed until they have accumulated sufficient data to demonstrate the device is safe and effective.

Q Now, during and IDE period may a company sell one of its investigational devices?

A A company can charge for the device, which is, I presume the same as you mean they sell. In other words, they can recover cost for the device. The cost can exceed the amount necessary to recover the research of cost that went into the device and the handling and the cost of the investigation itself.

Q Now, once the IDE data has been compiled, what is the next step in obtaining a PMA for a device such as an implantable cardioverter or defibrillator?

A Well, assuming the study went well and the data supported, the company would be expected to submit a pre-market approval application to FDA in which they would summarize the data, present all other animal and clinical data that they have accumulated, they would describe all of the manufacturing methods that are proposed to be used in making the device, they

would fully describe the technical details of the device, how [Veale — page 43] it is made, and they would provide a copy of the labeling and the operation of manuals that will be provided with the device.

Q Approximately how long is an IDE test period for a device such as an implantable cardioverter or defibrillator?

A Well, for a device like an implantable cardioverter or defibrillator, the test period would typically be, in my experience —

MR. MALLOY: Excuse me.

THE WITNESS: Two to three years.

MY MALLOY: I am going to object, Your Honor. We had testimony that this witness had no personal experience with this device. I think it is improper for him now to test about personal experience and his timing with this very device.

THE COURT: No, overruled. I think he has shown his expertise. If you want to ask him some questions about his background and qualifications, I will permit you to do that.

MR. MALLOY: I have a different — may I approach the bench?

THE COURT: Why don't you talk it over with Mr. Levin first.

(Discussion between counsel off the record.)

MR. MALLOY: Your Honor, I have a different objection and that is the question was "like implantable defibrillators," that's vague and indefinite. I think what Mr. Levin may have intended to say is some other device, not an implantable [Veale — page 44] defibrillator. I object to the vague and indefiniteness of "like an implantable defibrillator." If he wants to specify —

THE COURT: Well, Mr. Veale said, as I understood it, that an implantable defibrillator would come within a certain category, I forget what category it was, and I thought it was in that context that he was being asked a question. In other words, if it is category A, if implantable defibrillator is in category

A, what happens as far as category A is concerned. I don't believe that he has said that he can predict with absolute certainty that this device will have to be tested for 600 days plus 23 hours and 14 minutes. He hasn't come down with that, nor could anybody, but I think within the context of his testimony, the question is proper.

MR. MALLOY: Just so we understand he is not talking about personal experience with an implantable defibrillator.

THE COURT: All right.

MR. LEVIN: He has already testified to that.

MR. MALLOY: Okay.

BY MR. LEVIN:

Q Mr. Veale, I will repeat the question. How long is normally required for an IDE testing period for an implantable device such as a cardioverter or defibrillator?

MR. MALLOY: Well again, I am going to object, Your Honor, Cardioverter, defibrillator.

[Veale — page 45]

THE WITNESS: In my experience —

THE COURT: No, I will overrule your objection.

THE WITNESS: In my experience, I would expect the test period to require two to three years.

BY MR. LEVIN:

Q Is that because a device such as an implantable cardioverter or defibrillator is in class three as you have testified?

A It is because of the fact that it is a critical lifesaving device and also because it is considered a class three device, but primarily because it is of the nature of a lifesaving device and has to be exhausted of the testing.

Q And approximately how long does the FDA's review of a PMA application for a lifesaving class three device of this sort take?

A The FDA's PMA review process will almost always take at least one year from the time the application is first submitted until it is finally approved. For a product like this where FDA would be expected to extend an extensive amount of review to make sure the device is safe and effective, I would expect it to take longer and possibly as long as two years.

Q So then if a company wishes to ultimately market a class three medical device, it must first apply to the FDA for an IDE period of testing and after which it can apply to the FDA for a PMA?

[Veale — page 46]

A That's correct.

Q Each of which period requires some certain amount of time?

A That's correct.

Q In general, approximately how long would it take from the time the IDE is first granted until a PMA is obtained?

A For a product like the implantable cardioverter defibrillator, which is a lifesaving device, I would expect the entire process to take a minimum of three years and probably five or six years — five years or longer.

Q Would it make a difference in the FDA's deliberations or approval process whether the company which has filed for an IDE or a PMA has a patent license on its medical device?

A It would make absolutely no difference.

Q In general, does the fact that one company has received a PMA on a particular medical device make a difference to a second company seeking approvals of its own medical device? And let me restrict my question to class three devices.

A Well, in general, no, it makes no difference whether one company has received a PMA for a device or not. Each company must establish and submit a separate application for their own device.

Q And that means that a second company coming down the pike would have to go through the entire IDE testing and PMA application procedure?

A That's right.

[Veale — page 47]

Q Are you familiar with the term piggy-backing?

A Yes, I am.

Q And what does that term mean in FDA parlance, if anything?

A This would mean one company who is submitting a pre-market approval application or using the data that was previously submitted by another company on another product and using that data to support safety and effectiveness of their own product.

Q And is piggy-backing allowed within the FDA for class three devices?

A Well, for products that are required to go through the pre-market approval process, using data on another application on another device, this specific is specifically excluded. It is not allowed.

Q Are there any circumstances under which one company can use data already submitted by another company relating to a class three device, for example?

A The only instance that I would know would be if a second company bought the product from the first company, lock, stock and barrel. That is they bought the entire device, the entire technology, and proposed to produce the identical device and in effect they would be buying the pre-market approval application from the company as well.

Q In preparation for your testimony today, did you review any documents submitted to the FDA by Medtronic in order to receive an IDE for its Model 7215 PCD?

[Veale — page 48]

A Yes, I did.

Q I would like to show you Exhibits 1400, 1404 and 1405. Can you tell us what these exhibits are.

THE COURT: Give me the numbers again.

MR. LEVIN: 1400, 1404 and 1405.

THE WITNESS: These documents are the investigational device exemption application, the original application that was submitted by Medtronic for the Model 7215, an amendment to that application that was submitted by Medtronic on the same device and a supplement to that IDE application that was submitted by Medtronic.

BY MR. LEVIN:

Q Do these documents describe the design and operation of the Model 7215 device?

A Yes, they do.

Q And in preparation for your testimony today, did you review any documents submitted to or issued by the FDA which described the design and operation of Lilly's approved AICD product?

A Yes, I did.

Q I would like to show you Exhibits 1118 and 1438, and I will ask if you can identify those exhibits?

A This document is the summary of safety and effectiveness data that's issued by the Food and Drug Administration when they approve the automatic implantable defibrillator system pre-market approval application submitted by Cardiac [Veale — page 49] Pacemakers, Incorporated.

Q Which exhibit number is that document?

A 1438.

Q And what is Exhibit 1118?

A This document is the physician's manual for the CPI automatic implantable cardioverter defibrillator.

Q Are these the documents which you referred to as describing the design and operation of Lilly's approved device?

A Yes.

Q Assume, if you would, that the Model 7215 device was being developed not by Medtronic, but by Lilly. Could Lilly then rely on any of the data already submitted for its approved AIC device?

A No, they couldn't.

Q Any why is that?

A They are different devices. FDA would view them as completely different designs and completely different products requiring completely separate sets of clinical data to support their safety and effectiveness and different pre-market approval applications.

Q Well, what is the basis for your view that the FDA would view these devices as completely different?

A Well, they are different in electronic design and they also differ as far as the way they function; that is, they detect cardiac arrhythmias in a different way and they respond to [Veale — page 50] cardiac arrhythmias in a different way.

Q I would like to show you one more document I will place on the table there, Trial Exhibit 1426. Can you identify this document?

A This is the approval letter or actually a conditional approval letter issued by the Food and Drug Administration to Medtronic for the Model 7215 device?

Q You said Model 7215 device?

A Yes.

Q And have you reviewed this document in preparation for your testimony today?

A Yes, I have.

Q In preparation for today's testimony, have you also reviewed Trial Exhibit 755 which I will show you a copy of now?

A Yes, I have reviewed this document.

Q Can you tell us what that document is?

A This is the affidavit of Mr. John G. Keimel.

Q A Medtronic employee?

A Yes.

Q And in preparation for your testimony today, have you become aware of whether or not Medtronic has undertaken any implant in the United States pursuant to its conditionally approved IDE?

A Yes. According to Mr. Keimel's affidavit, there have been no implant in the United States of the Model 7215 under their [Veale — page 51] IDE, their approved IDE application.

Q Now, based upon your review of these documents and the other pile of documents that's sitting on the table there, do you have an opinion as to the time in which Medtronic is likely to receive full PMA approval for its PCD device?

A Well, considering the fact that they haven't started their clinical study yet and considering the fact that their IDE is limited to a maximum of 30 subjects at this point, my opinion is it will take them at least three and probably five or more years before they will be able to obtain final approval for their pre-market approval application.

Q And does the scope of this conditional IDE approval enter into your opinion?

A Certainly. They are only approved to implant the device in a total of 30 subjects and they will undoubtedly need several hundred subjects before they can obtain pre-market approval application, pre-market approval from FDA which means they will have to resubmit an IDE application at a later date to extend the study.

Q So then it is your opinion that Medtronic is unlikely to receive full pre-market approval opinion for at least three years?

A At least three years, yes.

MR. LEVIN: Thank you. I have no further questions.

CROSS-EXAMINATION

[Veale — page 60]

(End of a sidebar discussion.)

BY MR. MALLOY:

Q I want to ask you questions, Mr. Veale, about what is included in the term commercialization and what is not included in the term commercialization. Now, during the IDE proceeding, do you believe that Medtronic would be allowed — you have indicated that they shouldn't be allowed to commercialize; is that correct?

A Well, what I said is that the IDE regulation prohibits commercialization during the investigational stage.

Q Okay. Now, let's explore that term commercialization. Do you believe that under that provision that Medtronic would be able — would be allowed to charge a price for the PCD 7215 system in such a way as to allow head room for device improvements?

A I don't know that that specific reason would be suitable for justifying to FDA that a specific cost would be permitted.

Q Do you think that Medtronic would be allowed for their 7215 to price their structure in such a way as to allow competitiveness with the existing CPI unit called the AICD?

A Those aren't conditions that FDA would consider in supporting the cost.

Q Are you saying that would be impermissible?

A Those aren't the criteria that FDA review as far as the justification for the cost that's to be charged.

[Veale — page 61]

Q So that would be permitted under the FDA proceeding; is that correct?

A I am not saying that. What I am saying is that the criteria that FDA asks for would not include that.

Q Well, let me ask it this way: If the party came in, the second party, you have got one unit approved already, and then a second party came in with a similar unit, and revealed to you, to the FDA that they were going to charge a price and that they were going to set the price in such a way as to allow competitiveness with the existing already approved CPI unit, would that be permitted, if you knew that fact?

A I don't think that would be permitted as a justification for charge.

Q Now, if the party came in, in Medtronic came in and told you that the price they were going to set for their IDE unit, the PCD 7215, was going to be marginally premium priced compared to the competitive unit, the CPI unit, if you knew that fact, would that — would Medtronic be permitted to do that?

A The cost of competing units, as you put it, has no bearing on the cost of FDA approval or not.

Q So if you knew that fact, you would still permit Medtronic to go ahead and price their unit in such a way as to allow premium pricing compared to the competitive unit?

A If the costs are justified in terms of how much it cost to [Veale — page 62] run the study and how much it costs to produce the device, FDA would permit it.

Q Would Medtronic be allowed to come in under the IDE and set up — reveal to you that they are going to set a price for their unit, their IDE unit, called the 7215 in such a way as to allow downward price adjustment if necessary without sacrificing desirable gross margin?

A I am not sure I understand that question.

Q Okay. If they told you they were going to set their price in such a way and they were going to sell the unit at such a price that they could have room enough to lower their price later and still have an acceptable gross margin, would you permit that?

A The question FDA judges is whether the cost that's proposed for the device is supported by the cost that the company will incur in conducting the study or in reducing the device. The issues of competitiveness with other products has no bearing on the cost of the system that FDA will justify. In fact, if these points

are brought up, FDA would probably exclude those parts of the cost from coverage.

Q Which parts?

A The parts that are involved in the competitiveness; that is, the parts that are specifically identified as being — the parts of the cost that are specifically identified as being made to be more competitive or to compete with other products [Veale — page 63] or —

Q You mean they wouldn't want Medtronic to do that?

A That's right. They cannot use that as supporting the cost for the —

Q And if Medtronic did that and if you knew about it, the FDA would object to that conduct; is that correct?

A Not necessarily. The essential issue is whether the product is — whether they are charging enough for the product to cover their cost or not. Typically on a study of this nature, the actual cost involved with each patient or each implant far exceeds the cost that's actually charged.

Q Excuse me. I think you are going beyond my question.

MR. MALLOY: I know Mr. Levin would want him to continue, Your Honor, but I think he has gone beyond my question.

THE COURT: No, I don't think he is. I will permit it.

BY MR. MALLOY:

Q Okay.

A And in most cases, almost any charge can be justified for a device of this nature because of the extremely high cost involved in conducting clinical study.

Q Okay. So in the IDE study, would it be permissible to charge a cost for the unit which would be five times the cost of labor, burden and materials for the product itself?

[Veale — page 64]

A If the — I don't know that you can specifically say that. It is a question of whether the cost of putting the device together, the components and so forth justify. FDA realizes that each one of these devices in a study like this is essentially hand-made. In a study as early as this, devices are basically hand-made.

Q Well, excuse me, but you don't know whether the Medtronic device was hand-made or not.

A I have no idea whether it was or not. What I am saying is FDA's approach to these kind of situations that they recognize these products, the cost involved in per unit and implanting a device like this at this early stage of the clinical investigation is extremely high and they will generally adjust — generally approve almost any reasonable cost.

Q So for example, you are saying that the FDA would approve a cost if the cost of the unit were — let me say it the other way around. If the selling price of the unit were five times the cost of labor, burden and materials, and if you knew that fact, could Medtronic still get approval under 90E and sell its product for five times —

A If they can justify that cost they can.

Q Okay.

A For instance, the research cost that went into developing the device is a legitimate cost to include and charge and typically research, the research that went into a device like [Veale — page 65] this is quite large.

Q And so as long as the research costs weren't used up, you could charge almost anything you wanted for the units during the clinical, so long as you didn't use up the research cost; is that correct?

A As long as you can justify it on the basis of recovering the cost that went into developing the device and the costs that are involved in conducting clinical studies and producing each of the devices that are used in the clinical study.

Q Would it be permissible to use the IDE study to plan the elimination of a competitor?

MR. LEVIN: Objection, Your Honor. There is no foundation for this question.

THE COURT: I will sustain the objection.

MR. MALLOY: Would you hand the witness Exhibit 139.

MR. LEVIN: Your Honor, we have an objection to this exhibit.

THE COURT: Let me take a look at it. Why don't you talk it over between yourselves first.

(Brief pause.)

BY MR. MALLOY:

Q Would it be permitted in terms of your understanding of no commercialization to go out and tout the product under the IDE clinical as making the party who manufactured the IDE product the tachycardia leader of the world? Would that be permitted?

[Veale — page 66]

A The FDA frowns on making claims of safety and effectiveness about a device in advance of the device being approved. It doesn't care if a company promotes itself as making a device or being a leader in a field, so long as they don't make any overt claims about the safety and effectiveness of the device.

Q Would it be permitted to display the unit and demonstrate it at a worldwide cardiology convention to all the potential customers for the unit, even though those customers weren't planned to be investigators?

A It would be permissible to display it as long as the display is clearly labeled that it is an investigational device and that the device isn't available for commercialization.

Q Would it be permitted to do what's called pre-selling to educate the potential customers of the unit to its features and to indicate that this was going to be a device coming down the pike?

A I am not sure what you mean by pre-selling, but if I understand it to mean offering it before it is available, offering it before it is actually available, I think FDA would consider that commercialization.

Q Would it be permissible under an IDE to use the product under the IDE and then to proclaim to all the potential customers, regardless of whether they were going to be involved in the IDE or, to proclaim to them that Medtronic will be the major supplier of implantable defibrillators and that — and [Veale — page 74] that not on any personal experience with implantable defibrillators; correct?

A That's right.

Q And not on any understanding or information about where Medtronic is with respect to its manufacture of the 7215 or further, 7216 units; is that correct?

A That's correct.

Q And Medtronic, as far as the FDA is concerned, can manufacture all the units it wants in the United States so long as the units aren't assembled from top to bottom and then ship them into Canada or some other country without FDA approval; is that correct?

A As long as the — an unapproved device isn't shipped in Interstate Commerce in the United States, that's correct. FDA would consider an assembled device with a packaged for use to be a product that would be shipped in Interstate Commerce that would be subject to FDA's regulations.

Q So as long as they keep it in two parts, they can ship it out, put it together?

A Well, within reasonable constraints, that's the case. The bottom line, if you will, on FDA's regulation of those sort of situations is that the product that's going to be commercialized can't be shipped in Interstate Commerce.

Q And in all your testimony today, you are not appearing here as an expert to say whether or not any patent is infringed?

DAY 13 TRIAL TRANSCRIPT
[page 10]

Lee's deposition, page 96, Your Honor, and we have the very same objection.

MR. JOHNSON: Your Honor, if I may, I would like to read the two questions.

THE COURT: Sure.

MR. JOHNSON: Or three questions that are involved here.

MR. MALLOY: What page?

MR. JOHNSON: This is page 70, and 71.

"How has CPI been harmed, if it has been, by Medtronic's activities with respect to its PCD?

"Answer, I don't know.

"Do you know of any damages at all to CPI as a result of Medtronic's tests concerning its PCD?

"I don't know.

"Do you know of any?

"No, I don't. I don't know.

"Do you know of any sales of CPI devices which have been lost to Medtronic?

"As I stated earlier, the two implantable devices in Canada perhaps have been lost sales in those patients who needed an implantable high energy defibrillator. I do not know that. I do not know the situation involving those two patients who had received this device, if in fact there were two patients in Canada."

DAY 13 TRIAL TESTIMONY OF JON LEE
[page 100]

MR. JOHNSON: Page 96, line 15.

"BY MR. JOHNSON:

Q Do you know of any VENTAK sales which have been lost to sales of Medtronic devices?

You can answer the question.

A Probably the units that were implanted in Canada, Medtronic units implanted in Canada.

Q Do you know whether the physician who implanted units in Canada was authorized to implant VENTAK units?

A I don't know.

Q Do you know whether the conditions of the patients involved in Canada were such that they might have been eligible for implantations of VENTAK devices?

A I just don't know.

Q What information do you have, if any, that indicates to you that the — any implants of Medtronic devices in Canada resulted in lost sales to CPI?

A I am only speculating."

MR. JOHNSON: Do you want your designation at 132?

MR. MALLOY: Yes.

"BY MR. JOHNSON:

Q Is its market share increasing or decreasing in the pacer area?

A It's increasing."

DAY 13 TRIAL TESTIMONY OF
PAUL W. WYLIE
[page 161]

Given these factors, I would expect that Medtronic would open with an offer of about three percent for a license and I would expect that Intec would counter for something much higher than that and there would be back and forth negotiation.

I think the factor that might tip the scale here would be that Medtronic did not have to do their experimentation even for U.S. FDA purposes in the United States. They could do it

outside the country and submit the data from implants outside the country to the FDA to obtain their approval. Medtronic had a plant in the Netherlands and I understand that all of the 7210 devices came from the Netherlands plant, so it might have been an easy enough matter for them to conduct this experimentation outside the United States.

DAY 18 TRIAL STIPULATION
[page 29]

THE COURT: Good morning, ladies and gentlemen. I apologize for the fact we were not ready for you on Thursday, we were not ready for you on Friday and that we have kept you waiting this morning. I hope this will be your last wait.

As I told you before, the evidence is closed, but the parties have agreed that there is one additional bit of information evidence which comes to you in the form of a stipulation and this in effect is one more bit of evidence.

Now, a stipulation is exactly what you think it is. It is an agreement by the parties that facts which are related in the stipulation can be accepted as true without any further proof. This is what the stipulation says. "The parties have agreed that the selling price of Medtronic 7210 device was \$10,000. The parties have also agreed that the selling price of Medtronic's PCD Model 7215 was \$17,000."

**DEPOSITION TRANSCRIPT OF
TERRELL WILLIAMS**
[page 202]

Q Where did you see the memo?

A Where was I?

Q Yes.

A At Medtronic.

Q Where in Medtronic? Were you in your office?

A I don't remember where I was when I saw the memo.

Q Did you receive a copy on your desk?

A I'll take that back. I could have read it at home if I had thrown it in my briefcase.

Q Who wrote the memo?

A I think it was Jack Keimel.

Q Tell me in words or substance what the memo said.

A The memo said we won't now or in the future market release the 7215.

Q Did it give any reasons?

A Let's see, no, I don't think they did.

Q Was it a one-sentence memo?

A No, it was — I think it dealt with other topics, too.

Q Had you ever heard that Mr. Griffin had a different view with respect to whether or not the 7215 would be market released?

[Williams - page 203]

A Oh, I imagine he probably did when they started the project.

Q And what is your understanding of Mr. Griffin's view today?

A His view today is that it won't be market released, that's pretty clear.

Q What do you mean by "market released"?

A That means commercial distribution.

Q Did the memo indicate how many units of the 7215 would be sold at any time?

A I don't recall.

Q Now, you didn't interpret that memo to mean that the Model 7215 wouldn't be sold, did you?

A No, I said market released.

Q All right. It's your understanding that it is Medtronic's full intention to go ahead and sell the Model 7215?

MR. LEVIN: I'll object to that question.

BY MR. MALLOY:

Q Correct?

A What we — we get back a certain amount of reimbursement for devices that we distribute but it is not a commercial venture. It doesn't provide positive cash flow.

Q Well, when you say it doesn't provide

**DEPOSITION TRANSCRIPT OF
LARRY BOWLING
[page 13]**

provided reprints of published articles to people that requested information about the device. But that was the only education, if you want to call that education, that we provided.

Q Are you finished with your answer?

A Yes.

MR. LEVIN: Off the record.

(Whereupon, there was a brief discussion held off the record.)

Q As part of your responsibilities during this time period, or starting in 1984, did you or anyone on your staff bring posters or prototypes or other information regarding the AID-B device to meetings, for example, of the American Heart Association?

A Yes. We had a booth at the American Heart Association which had the things you described in it.

Q Did you have a booth every year at the American Heart Association meeting?

A Yes, we did.

Q Starting in 1984?

A Starting prior to that.

[Bowling — page 14]

Q Did you have booths at any other meetings attended by cardiologists or physicians?

A We had a single booth. It was a very small limited booth which basically showed the device and where it was implanted. We passed out literature. There was a sign in the booth that said device in clinical investigation, not for sale, which is required by the FDA. We attended, initially, two meetings.

Q Per year?

A Per year, the American College of Cardiology, and the American Heart Association. Later we started going to the North American Society of Pacing and Electrophysiology convention.

Q At these meetings, were physicians and cardiologists who had not yet received approval from the FDA to participate in the clinical trials eligible to come to your booth and receive information about the AID or AID-B devices?

A Yes.

Q Was it your desire that they come to the booth to use that information?

A Yes.

[Bowling - page 15]

Q Was it the intention of setting up these booths at these meetings to develop interest in not then participating cardiologists or physicians who would then try to or who would then later become part of the clinical trials?

MR. SHIFLEY: Objection. Leading.

A The primary purpose of the booth was information, to disseminate information about the automatic implantable defibrillator. Our hope was that we would develop a certain amount of interest in the device so that once it was approved by the FDA we could begin to market it and we would have a reservoir of physicians' names that we could then contact.

Q Is it correct then that you do not consider setting up a booth at an AHA meeting, ACC meeting or a meeting of the Society of Pacing and Electrophysiologists to be marketing?

MR. SHIFLEY: Objection. Leading, beyond personal knowledge, calling for an opinion as opposed to factual testimony, asking the man for expertise about knowledge he doesn't have. Go ahead and answer.

[Bowling - page 16]

A A booth can have many different purposes at a meeting. It can provide information. It can be there for marketing purposes, or you can conduct surveys, many, many different reasons. Because the FDA strictly prohibits a company from marketing a product until it is approved, then we could not do that. So our purpose was information. We disseminated clinical papers that were published and answered questions regarding the status of the investigation.

Q Is it correct then that you considered the dissemination of that information and the display of the devices at these booths during the time, that they were in clinical trials not to be marketing?

A In my definition of marketing, yes.

Q Your definition of marketing is what?

A We were not soliciting to sell the device or to expand sales of the device, because we couldn't.

Q Was Intec receiving revenue for its providing of the devices to implantation centers during the clinical trials?

A Yes.

[Bowling - page 17]

Q Was that sales of the devices?

MR. SHIFLEY: Same objection as past.

A You know, again, we were able to recover a portion of our cost for manufacturing and the training and all of the other things that were involved in having that device available for

implant. We billed the customer for that. We did not recover the full cost of the device during that period of time.

Q Are you finished with your answer?

A Yes.

Q Do you know whether or not Intec was losing money in 1984?

A Yes, I do.

Q Was it?

A Yes.

Q Were part of your responsibilities at Intec starting in 1984 to expand the scope of the clinical trials in order to bring more revenue into Intec?

MR. SHIFLEY: Objection. Leading, asked and answered.

[Bowling - page 90]

University of Indiana, [sic] an Intec device could not be implanted?

A At the University of Indiana. [sic] They could have been implanted at others, as was the case of several patients of his.

Q Do you know of any particular implantation of a Medtronic device during the time you were at Intec which implantation deprived Intec of having its own device implanted in that patient?

A I don't know of any.

MR. LEVIN: Let's take a short break.

(Whereupon, there was a brief recess taken.)

Q Mr. Bowling, did there come a time when you became aware that Intec Systems had filed a lawsuit against Medtronic?

A Yes.

Q For alleged infringement of two Mirowski patents under which Intec was licensed?

A Yes.

Q Did you take part in the consideration within Intec of whether or not to file that lawsuit?

DEPOSITION TRANSCRIPT OF JON LEE
[page 96]

defibrillation thresholds by orthogonal, time-separated shocks?

A I don't remember, probably because I don't quite understand it.

MR. SHIFLEY: You are not alone.

BY MR. JOHNSON:

Q Has CPI been financially damaged in any respect by Medtronic's alleged infringement in this lawsuit?

A Not that I am aware of.

MR. SHIFLEY: Let me state for the record I don't expect this man to be an expert as to damage. He is here as to marketing. Again its personal opinion and not a 30(b)(6) opinion.

BY MR. JOHNSON:

Q Do you know any Ventak sales which have been lost to sales of Medtronic devices?

MR. SHIFLEY: Again, this is not a 30(b)(6) witness on this topic. You are getting personal opinion.

BY MR. JOHNSON:

Q You can answer the question?

A Probably the units that were implanted in Canada. Medtronic units implanted in Canada.

Q Do you know whether the physician who implanted units in Canada was authorized to implant Ventak [Lee — page 97] units?

MR. SHIFLEY: Do you know if he needed authorization to do so. As a preliminary go ahead and answer.

THE WITNESS: I don't know.

BY MR. JOHNSON:

Q Do you know whether the conditions of the patients involved in Canada were such that they might have been eligible for implantation of Ventak devices?

A I just don't know.

Q What information do you have, if any, that indicates to you that the — any implants of Medtronic devices in Canada resulted in lost sales to CPI?

A I am only speculating.

Q You have no firsthand knowledge of information?

A No.

Q From time to time did CPI present information concerning its Ventak devices at regular professional society meetings?

A Yes.

Q Does it encourage its investigators to present information concerning its — their clinical experience with Ventak devices?

A Yes.

DEPOSITION TRANSCRIPT OF
BRUCE RAYKOWSKI
[page 70]

If that's — I don't know that.

Q What is the current market share of CPI in the cardi-overter defibrillator area?

MR. MALLOY: I'm going to object to the term market if you're using it in an economic sense, Counsel, or a legal sense. But to the limited lay extent the witness has, he may answer, if he knows.

A I would assume — We are the only company today manufacturing an AICD. If it's the market that you're referring to, I would assume that we have 100 percent.

BY MR. JOHNSON:

Q How has CPI been harmed, if it has been, by Medtronic's activities with respect to it PCD?

MR. MALLOY: Don't speculate or guess. He is asking you what of your own knowledge.

A I do not know.

BY MR. JOHNSON:

Q Do you know of any damage at all to CPI as a result of Medtronic's tests concerning its PCD?

A I don't know.

[Raykowski — page 71]

Q You don't know of any?

A No, I don't.

MR. MALLOY: Counsel, I think the question is objectionable, because the witness has already testified that he has a limited knowledge about the device, itself.

A I don't know.

BY MR. JOHNSON:

Q Do you know of any sales of CPI devices which have been lost to Medtronic?

A As stated earlier, the two implantable devices in Canada perhaps have been lost sales, if those patients needed an implantable high energy defibrillator. I do not know that. I do not know the situation involving those two patients that received this device, if in fact there were two patients, in Canada.

Q Are you speculating?

A I don't know.

Q You don't know whether you are speculating?

MR. MALLOY: Counsel, you're realling [sic] arguing with the witness.

MR. JOHNSON: I'm not arguing. I'm just asking whether he has factual

PX-54

MEDTRONIC

Medtronic, Inc.
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Minneapolis MN 55432 USA
Telephone (612) 574-4000
Cable Medtronic Telex 29-0598

April 25, 1986

Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

RE: Supplement to IDE Number G830084

Termination of the Medtronic Model 7210 Clinical Study

Gentlemen:

The purpose of this letter is to inform you of our intention to terminate the Medtronic® Model 7210 Multiprogrammable Tachycardia Control System clinical study in accordance with Part 812.150(b) (7). A letter to the Model 7210 investigators will be sent shortly. A Final Report will be submitted to FDA, all reviewing IRBs and participating investigators in about one month.

Medtronic considers the contents of the IDE submission to be confidential commercial or trade secret information and requests it be given full protection under the law. This letter is submitted in triplicate in accordance with the IDE Regulation.

If further information is required please contact the undersigned.

Sincerely,

MEDTRONIC, INC.

/s/ TIMOTHY J. JOHNSON
Timothy J. Johnson
Product Regulation Manager
(612) 574-3482

CVS

PX-91

MEDTRONIC

INTER-OFFICE MEMO

TO:	Alain Rigal	cc:	Ed Duffin
FROM:	T.V. Rao		Bill Erickson
DATE:	December 31, 1986		Jake Gjoraas
SUBJECT:	MODEL 7215 PCD™—PRICING		Jim Grams
			Bobby Griffin
			Tim Johnson
			Mike Kallok
			Jack Keimel
			Gerard Planchon
			John Roberts
			Marty Rossing

Model 7215 PCD™—Medtronic pacer—cardioverter-defibrillator is a first of its kind for Medtronic. It represents major breakthroughs for Medtronic in the field of tachyarrhythmia implantable devices. It also represents major breakthroughs in technology available to physicians to manage their tachyarrhythmia patients. The following are some of the considerations reviewed in arriving at a price for the above system.

- Relative to other Medtronic products, PCD™ is highly sophisticated and extremely complex and demands a premium price compared to the highest priced brady product.
- Relative to the AICD™ (\$10,500) implantable pulse generator, PCD™ has
 - Lower maximum deliverable energy
 - Higher technology and sophistication
 - Smaller in size where size matters
 - A market that is dying for it (pun intended)
- The demand for the PCD™ system is extremely high today as evidenced by
 - Constant pressure from EPs to be investigators
 - Customer pull
 - The insatiable demand created by Intec

- The reimbursement scenario is as follows:
 - Approximately \$22,000 for first implant including the procedure (DRG 104).
 - Average cost of the procedure is \$35,000 according to ACC letter to HCFA.
 - Replacement DRG 117 pays only \$8,000.
- The PCD™ system
 - Safety and efficacy remains to be proven through clinical studies.
 - Energy level may limit its indications.
 - Has sophisticated pacing therapies that may avert VF.

Alain Rigal
December 31, 1986
Page 2

- Other competitive, comparable systems include:
 - AICD (CPI)—Defib only—approved.
 - Guardian (Telectronics)—Defib + brady.
 - ?? (Intermedics)—Potentially sophisticated.
 - ?? (Ventritex)—Presumed sophisticated.
- The PCD™ system pricing should
 - allow head room for device improvements
 - allow competitiveness with existing AICD
 - be marginally premium priced compared to AICD
 - prevent undue price visibility
 - limit head room for less sophisticated devices
 - allow downward price adjustment if necessary without sacrificing desirable gross margin
 - encourage use of system purchase concept
 - not discourage prophylactic patch implant

Based on the above considerations, the following pricing structure has been established.

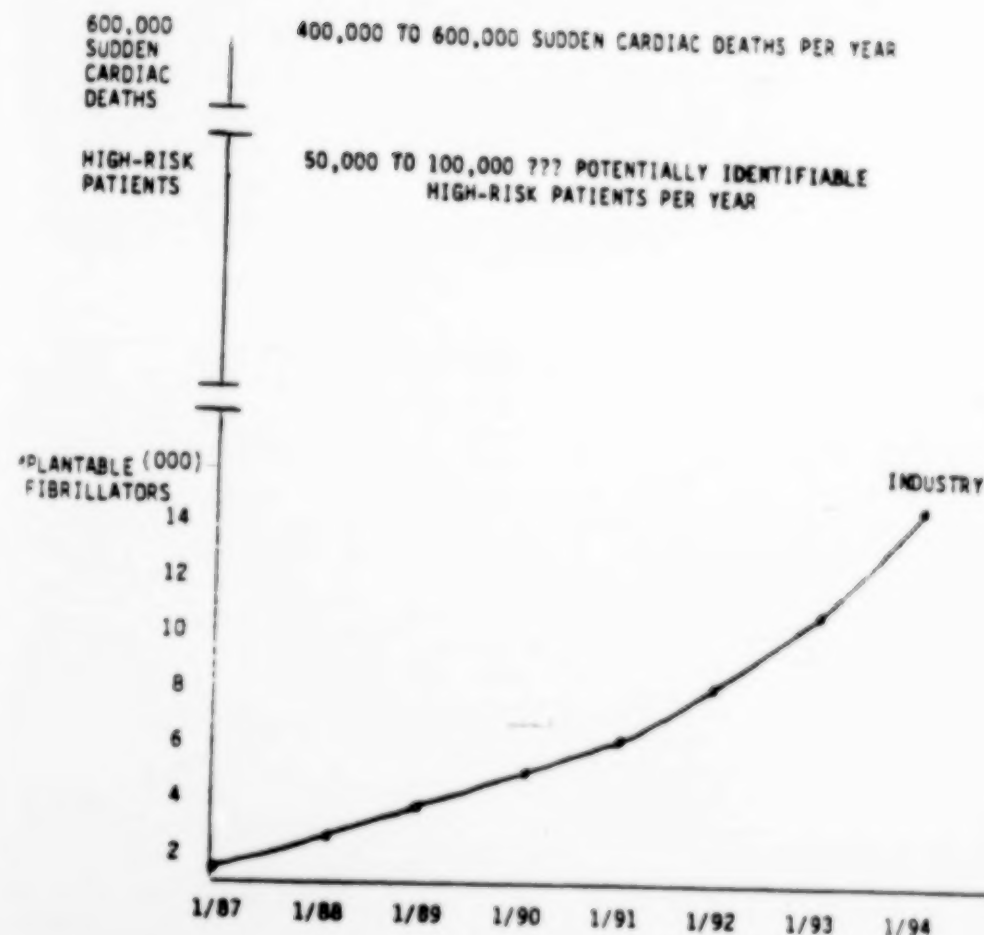
Model 7215 PCD™ Implantable Pulse Generator	\$12,500
(3) Patch leads (Models 6888, 89 or 90) at \$950 ea	2,850
(1) 6917 screw-in epicardial lead	600
(1) 6886 adaptor	250
Total	\$16,200

The PCD™ system price consisting of the above components would be \$15,500 if they are purchased as a system resulting in a \$700 discount.

MP12/4293D

PX-139

THE IMPLANTABLE DEFIBRILLATOR MARKET & U.S. MARKET POTENTIAL



ASSUMPTIONS: EARLY '90s

- Diagnostic improvements (E.P., CAD, Ejec. Frac.)
- General acceptance of E.P. by C.D.
- Grow acceptance of screening criteria
- Non-thorocotomy implant

PCD UNIT/REVENUE PROJECTION

			PAST	\$15,000
		(000)	(000)	(000)
	Units	Revenue	Revenue Cum.	Costs Cum.
FY'88 (7215)	60	\$ 600	\$ 600	\$18,000
FY'89 (7216)	240	2,400	3,000	18,700
FY'90	800	8,400	11,000	21,000
FY'91	3,200	36,400	47,800	21,800
FY'92	4,500	44,600	92,000	22,600

AssumptionsPrice

- U.S. \$12,000
- INTERNATIONAL \$8,000

UNIT SPLIT DURING CLINICAL

- U.S. 50%
- INTERNATIONAL 50%

UNIT SPLIT MARKET RELEASE

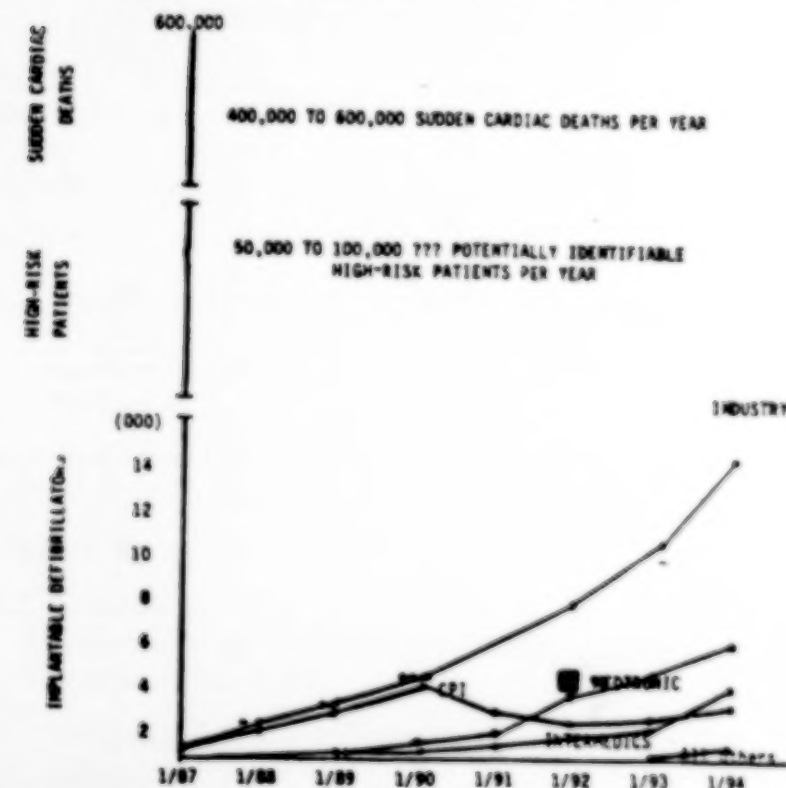
- U.S. 75%
- INTERNATIONAL 25%

COST: VARIABLE/SYSTEM = \$3,000/SYSTEM
(INITIALLY = \$3,600/SYSTEM)

HISTORICAL INVESTMENT

AID	\$ 1.0 MIL
Zsx	3.3 MIL
PCD ₁₅	7.7 MIL
MARKETING	3.0 MIL
TOTAL PAST	\$ 15.0 MIL

THE IMPLANTABLE DEFIBRILLATOR MARKET & U.S. MARKET POTENTIAL

ASSUMPTIONSCPI

- * Supply problems
- ** Ventak P released
- *** Ventrak PRX released

Telectronic

Not a factor

Ventrifex

Is acquired by Medtronic, however if acquired by Siemens-Pacesetter they will command 10-20 share by 1992.

Medtronic

Achieves current plan, including International release of 7216 summer 1989. U.S. release early 1990 with a transvenous lead during 1990.

Intermedics

Starts clinical of a "PCD" device during 1983 and achieves approval 30 months later.

PROJECTED TACHY UNITS/REVENUES

	<u>FY'88</u>	<u>FY'89</u>	<u>FY'90</u>	<u>FY'91</u>	<u>FY'92</u>
5326/28 UNITS	84	50	25	20	20
\$ (000)	\$ 732	\$ 435	\$ 217	\$ 174	\$ 174
7008 UNITS	12	20	6	—	—
\$ (000)	\$ 72	\$ 120	\$ 36	\$ —	\$ —
5998 UNITS	12	12	12	—	—
\$ (000)	\$ 24	\$ 30	\$ 30	\$ —	\$ —
PCD UNITS	57	240	800	3,200	4,500
(7215/7216)					
\$ (000)	\$ 600	\$ 2,400	\$ 8,400	\$ 36,400	\$ 44,600
MESA UNITS	5	40	50	60	60
\$ (000)	\$ 100	\$ 1,000	\$ 1,250	\$ 1,500	\$ 1,500
EP MEM MOD					
UNITS	—	300	100	50	50
\$ (000)	—	?	?	?	?
<hr/>					
ANNUAL REVENUE					
\$ (000)	\$ 1,528	\$ 3,985	\$ 9,933	\$ 38,074	\$ 46,274

PX-142

MEMORANDUM

TO: Medtronic Jerusalem Attendees
 FROM: Mike Toffoli
 DATE: June 3, 1987
 SUBJECT: TACHYCARDIA MANAGEMENT SYSTEMS

POSITIONING STATEMENT FOR JERUSALEM:

- A. Medtronic will be the major supplier of implantable defibrillators, and external E.P. stimulators . . . "Doctor your medium/long range partner in tachy control devices is Medtronic."
- B. Medtronic will be a key contributor in advancing the science relevant to tachycardia detection and therapy.

STRATEGY:

- A. Expedite the PCD development and clinical evaluation achieving a releaseable (International) 30 joule system by summer 1989.
- B. Develop a thorough understanding of electrophysiology and design/supply instrumentation that improves the electrophysiologists productivity, accuracy, etc.
- C. Short term, leverage education programs and research projects that will build credibility and rep relationships critical to future success.

TACTICS:

PCD (pacer-cardioverter-defibrillator) clinical will begin in June 1987 (Canada). This 15 joule output device is the first to offer "staged electrical therapy." It is very programmable, providing the capability to tailor independent VT/VF detection criteria . . . the powerful VT detection algorithm, for example, can employ up to 4 criteria to define and qualify a VT! A variety of therapies can be tailored for VT including: premature stimulation, adaptive burst pacing, decremental overdrive pacing

and cardioversion. VF can be treated with up to 4 defibrillation shocks (programmable energy level).

This device, the 7215, is very sophisticated and is already being chronically evaluated in dogs. In humans, defibrillation thresholds of 10 to 25 joules are not infrequent, therefore, a 30 joule PCD is being expedited and will be introduced into the PCD clinical study in less than one year. It is this 30 joule PCD (7216) that we plan to release (International) during the summer of 1989.

Obviously, it is desirable to achieve a transvenous defibrillation system (or at least a "non-thorocotomy system). Medtronic's work on such a system began in the early 1980's with the implantable cardioverter and the 6880 leads. That lead work plus more recent efforts both in Minneapolis and at IRSC will result in transvenous and transvenous/subcutaneous patch lead systems that will be under clinical evaluation before the release of the 7216 PCD.

MESA, The Medtronic Electrophysiological System Analyzer, is another example of our commitment to attaining a leadership position as a supplier of stimulation equipment to the electrophysiologists.

This powerful and easy to operate system utilizes an IBM-AT coupled with a Medtronic atrial/ventricular stimulation interface, an eight channel signal acquisition interface, a unique keyboard and a powerful software program.

The MESA will avail the user automatic standard EP protocols, including:

- Sinoatrial conduction time
- Sinus node recovery time
- Atrial/ventricular effective refractory periods
- Atrial/ventricular arrhythmias induction
- A-V stimulation

and provide back-up therapies; including:

- Burst therapy (Fixed rate or rate adaptive), and
- SS1 pacing

MESA utilized four of the signal acquisition channels (high right atrium, HIS bundle electrogram, right ventricular apex and the surface ECG lead with earliest QRS) and a very reliable automatic cardiac event detection system to automatically record and analyze and generate EP reports. MESA significantly automates a currently labor/time intensive EP study.

Bottom line during the World Pacing Symposium we have to acknowledge that CPI now is the market leader in implantable defibrillators . . . they have 100% share and on that measure, no place to go but down! (At one time CPI had 100% of the lithium pacemaker market too . . . but . . .).

However, we must exude confidence and commitment that Medtronic will bring to the market tachy control systems that will certainly earn the market leadership position by the time we reconvene at the next World Pacing Symposium!

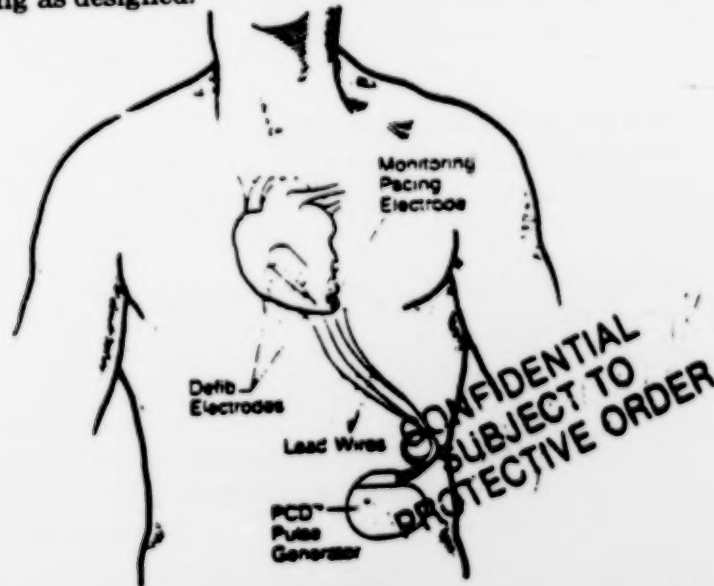
RAPID PULSE MEDTRONIC

JULY 2, 1987

First PCD Implant Launches Clinical Trials

The first implant of Medtronic's PCD—Pacer-Cardioverter-Defibrillator—occurred June 18 at the University of Western Ontario in London, Ontario. Surgeon Gerard Guiraudon and cardiac electrophysiologist George Klein implanted the PCD in a 45-year-old male who suffers from a form of tachyarrhythmia: recurrent ventricular tachycardia that deteriorates to ventricular fibrillation.

According to Fellow Mike Kallok, a research scientist on the project, the patient is doing well and, since the implant, has experienced one spontaneous arrhythmia which the PCD terminated successfully. "The implant went very well," says Kallok. "There were no problems during surgery and the device is performing as designed."



The PCD consists of a pulse generator containing the batteries, microprocessor, and related circuitry. It weighs about six ounces and measures about 3¼ inches long, 3 inches wide, and ¼ inch thick.

Four leads carry electrical signals between the pulse generator and the heart. One standard pacing electrode senses the heart's activity and paces the heart. The other three patch electrodes are sewn onto the outside of the heart and deliver shocks from the pulse generator to the heart. Each patch electrode measures approximately 2 inches by 3 inches.

Pacing Business Unit vice president Bobby Griffin says this first implant is significant for Medtronic. "We're now the technological leaders in the tachy arena. Despite stiff competition, it's our task to advance that position."

Treating Tachy

There are two types of tachyarrhythmias: atrial and ventricular. Atrial tachyarrhythmias currently may be controlled by drugs or pacemakers such as the Symbios 7008, now in clinical trials.

Ventricular tachyarrhythmias, on the other hand, can be very severe.

- Ventricular tachycardias (VT) cause the ventricles to beat so rapidly that they don't have time to fill with blood, thus drastically reducing cardiac output.
- Frequently, VT leads to ventricular fibrillation (VF), which results in a quivering heart muscle that is unable to pump any blood, often resulting in sudden death.

Medtronic's PCD is designed to monitor the heart rate continually and detect and treat these life-threatening episodes.

How PCD Works

The PCD detects episodes of ventricular tachycardia by measuring the time interval between each heartbeat. When the interval becomes too short, the device is designed to try to correct the rate with electrical therapies which become stronger as the episode continues.

The device combines pacing therapies, the 'P' in PCD, and low energy shocks called cardioversion, the 'C', to end the episode. If the device detects ventricular fibrillation, it will deliver higher energy shocks called defibrillation, the 'D' in PCD.

The device delivers only as many therapies as needed to stop a tachyarrhythmia. A series of VT or VF therapies can range from one imperceptible pacing sequence to up to four shocks.

The PCD's memory stores crucial facts about the patient's heart rate, device operation, and therapies delivered. Physicians may retrieve this information during checkups.

Patient Benefits

Each year in the U.S. alone, an estimated 400,000 cases of sudden cardiac death probably begin with ventricular tachyarrhythmias.

Drugs and surgery are the usual treatments for VT and VF, but for many patients surgery may not be an option and drugs may be ineffective or cause adverse side effects.

Because the PCD is designed to treat tachycardias promptly, patients may have shorter episodes of tachycardia and may avoid fibrillation. If fibrillation occurs, prompt termination may avoid later complications.

Compared to the shocks delivered with external defibrillation paddles by emergency medical teams, each PCD defibrillation shock is delivered at 25 times less energy. This avoids a burning sensation to the patient's skin associated with the external paddles.

Delivery What The Doctor Ordered

Medtronic's current tachy venture started with a complete analysis of customer requirements by marketing, engineering, and research.

"The PCD has been designed to fulfill our customer's requirements," says director of tachyarrhythmia marketing Mike Toffoli. "Electrophysiologists have asked for a system that 'does it all.' They want a device capable of bradycardia pacing, tachycardia overdrive pacing, cardioversion, and defibrillation. The PCD does all those things. It is a significant achievement for Medtronic.

"The business implications for the company are many," continues Toffoli. "Sudden death is a significant problem begging for a solution and the PCD device is the desired solution."

Status Of Clinical Trials

This first implant marks the start of the device's clinical trials, a crucial part of the product approval process. More clinical implants are scheduled in Canada. Clinical trials will begin in the U.S. when the Food and Drug Administration approves the PCD investigational device exemption. Approval is expected sometime this summer.

Tachyarrhythmia Management Bulletin

Bulletin #3, July 10, 1987

MEDTRONIC TACHYARRHYTHMIA MANAGEMENT OBJECTIVES & STRATEGIES

OVERALL OBJECTIVE: to be recognized as the research, technology, product and market leader in tachyarrhythmia control devices.

BUSINESS

Strategy: Focus on ventricular tachycardia and ventricular fibrillation segment. (That's where the medical challenges, volume and profits are.)

MARKET DEVELOPMENT

Strategy: Begin to establish a relationship with electrophysiologists now by marketing diagnostic stimulators and by establishing a leadership role in market education regarding tachyarrhythmia diagnosis and therapy.

Tactics FY '88

- Sell currently available products (Models 5328 and 5998 Stimulators); and introduce the EP MemoryMod this year and the MESA System next summer.
- Leverage market development and market education through courses such as "How to Approach Complex Arrhythmias (September, 1987 and February, 1988).
- Inform national sales force about product/program status and rationale with regular tachyarrhythmia bulletins starting in July, 1987.

- Increase sales force confidence with EP terminology and discipline so consultative relationships with EPs are possible — soon!

PRODUCT DEVELOPMENT

Strategy: Rapidly develop diagnostic stimulators and an implantable defibrillator that meets market requirements and norms (30 joule output, bipolar sensing), then advance science of VT/VF control. (Get in the game, then win the cup.) Leverage our powerful global distribution system to achieve a dominant market share position.

Tactics FY '88

- Begin clinical evaluation of the 15 joule Model 7215 PCD device and supporting instrumentation in June, 1987. This clinical base will be "applied" to the FDA submission for market approval of the 30-joule Model 7216 PCD to help expedite approval.
- Begin clinical evaluation of the 30 joule Model 7216 PCD May, 1988.
- Introduce the Model 9780 EP Memory Mod during the fourth quarter, FY 1988. Target promotional efforts at EPs with pacing practices.
- Introduce Model 2390 MESA (Medtronic Electrophysiological Systems Analyzer) Spring/Summer, 1988, aiming promotions at EP centers.

RESEARCH

Strategy: Gain a better understanding of EP mechanisms, sensing, detection, therapeutic requirements and lead configurations. Leverage relationships with key research centers and opinion leaders to achieve and sustain perceived product and technical market superiority.

Tactic FY '88

Continue research to advance detection and treatment of tachyarrhythmias with several funded projects.

PX-579

Medtronic

INTER-OFFICE MEMO

TO: Dwight Warkentin
 FROM: Mike Toffoli
 DATE: 8 April 1987
 SUBJECT: Tachy Objectives, etc.

Attached is a brief outline of objectives, strategies, and tactics as I see them.

Position for Jerusalem should be: Medtronic is making major strides toward a future leadership role in tachyarrhythmia management on several fronts as represented by our first clinical implant of PCD in June, 1987. We should indicate that clinical is beginning on a "staged electrical therapy" device. This early clinical device will have extensive programmability, telemetry, detection schemes, and three levels of therapy including: 1) low energy burst, 2) synchronized cardioversion, and 3) defibrillation up to 15 joules. We should acknowledge tht 15 joules will not be adequate in all patients and a 30 joule device will follow the initial PCD into clinical in less than 1 year. The Instrument support system around the PCD implantable systems is very strong and will include a "Prescription Formulator", programmer, and specialized follow-up equipment.

Additionally, the EP Mem Mod and the MESA will give us a very strong presence in the diagnostic end of the Electrophysiology business.

/s/ M. TOFFOLI

Tachyarrhythmia Management Systems

Mike Toffoli
 8 April, 1987

Objectives:

Be the recognized technology, product and market leader in tachycardia control devices by 1990.

Strategy:

- Focus on the VT/VF segment.
- Enter the market ASAP with a system that will satisfactorily treat ventricular arrhythmias (fulfilling market norms), and leveraging our powerful global distribution system to achieve a dominant market share. (Norms . . . Bipolar Sensing, 30 joule output ect.)
- Gain a superior understanding of the electrophysiological mechanisms and the required sensing, detection, therapeutic, and lead configuration/tissue interface requirements to achieve and sustain superiority.
- Rapidly develop product that meets obvious market requirements (and norms) . . . then advance the science of VT/VF control.
- Establish a relationship with electrophysiologists now through the marketing of diagnostic stimulators and establishing a leadership role in market education regarding tachyarrhythmia diagnosis and control.

Tactics FY'88

- "Harvest" the 5998 and 7008 system eg., continue to sell but without further business investments.
- Sustain sales levels of the 5326/28 EP stimulators with low level investment in sales force/customer awareness.
- Introduce the 9780 EP Mem Mod in January 1988 with promotional efforts targeted at EPs/cardiologists with pacing practices/influences.

- Introduce MESA electrophysiological systems analyzer in January 1988 with promotional efforts targeted at EP centers. (See the attachment for a brief description of MESA.)
- Began clinical evaluation of the implantable PCD system and related instrumentation in June, 1987.
- Expedite development of the 7216 30 joule PCD system and phase the 7216 into the PCD clinical evaluation by May of 1988.
- Continue and intensify market development/education activities through courses such as "How To Approach Complex Arrhythmias", etc. Create a presence through education where we lack hardware. (Sept. 1987 & Feb. 1988)
- Continue research in those areas likely to advance the detection and treatment of tachyarrhythmias (several projects are in process).
- Better inform the distribution system on product/program status, and rational. First Tachyarrhythmia management bulletin to be published July 1987.

PRODUCTS to be displayed in Jerusalem.

The PCD system:

- * 7215 pulse generator
- * Implantable Lead System
- * 9710 Programmer

The 5328 Stimulator

PRODUCT DESCRIPTIONS to be presented
(3 ring binder)

- * MESA
- * E P Memory Mod.

EDUCATIONAL COURSES to be offered

"How to approach complex arrhythmias."

Medtronic

PX-646

INTER-OFFICE MEMO

TO: George Heenan
FROM: Bill Engle/Jerry McCauley
DATE: December 29, 1977
SUBJECT: AUTOMATIC IMPLANTABLE
DEFIBRILLATOR

[p. 5342]

Enclosed please find the rough draft of the automatic implantable defibrillator (AID) venture analysis. Most of the material is in the final form, although the financial analysis is in rough draft form and the program plan and budget are not yet completed. These will be finalized by our January 4 meeting.

We would like to make the following recommendations, assuming that the financial projections in the AID report meet the Corporate criteria for new products:

- 1) Dr. Mirowski appears to be in a position of controlling all relevant patents relating to AID technology.
 - a) Discussions with Mirowski/Medrad should be undertaken to determine options available to Medtronic.
 - b) Begin negotiating appropriate agreements.
- 2) Negotiate with Purdue University on minimal funding necessary to maintain their involvement until a positive or negative indication of willingness to negotiate is obtained from Mirowski/Medrad.
 - a) We suggest that 4-6 weeks time frame is reasonable to determine that an equitable position for Medtronic can be worked out.

- b) Suggest that funding for Purdue to begin animal studies (4-6 dogs) be approved at an approximate cost of \$7,000.
- 3) Obtain a legal opinion of the AID patents internally or from a consultant.
- 4) Initiate the minimum internal activities necessary to:
 - a) Start battery study.
 - b) Design circuit breadboards.
 Estimated cost not to exceed \$8-10K over the six weeks.
- 5) All work on AID program should cease if negotiations are not satisfactorily resolved.

[p. 5363]

V. PROBLEM AREAS/RISKS

A. PATENTS

Dr. Mirowski has been issued several patents in the area of implantable defibrillation. We also know of at least one patent that is pending. Mirowski holds a *very basic* patent on automatic implantable defibrillators. After consultation with our Law Department, it appears it may be impossible to develop an AID without infringing on his patent. It is possible that we could fight his patent and the courts would find the patent invalid, but that is a very costly and very risky alternative.

A preferred approach would be to obtain a license under his patents. To the best of our knowledge, Mirowski has granted Medrad, Inc. an exclusive license to his patents. If the AID appears to be a worthwhile venture to Medtronic, Medrad and Mirowski may be receptive to a fair business proposal. Under our previous agreement with Mirowski we agreed to pay royalties of 4% on external sales and 3% on implantable sales. (We would probably have to increase royalties somewhat.) In addition to the basic patent,

Mirowski has applied for a patent covering the technique for sensing mechanical activity described elsewhere in the report.

On the positive side, Medtronic has or will receive several relevant patents. Rollin Denniston and Tom Davis, both former employees, assigned a patent to Medtronic that deals with sensing more than one parameter for the detection of fibrillation. The status of this patent is somewhat confused. Medtronic has agreed that Mirowski should be named as co-inventor. However, it is not clear whether or not Mirowski will receive a license to practice that invention.

Since Mirowski has applied for a patent for mechanical sensing, why isn't he developing it? We only know that he isn't publishing or discussing that technique. The device he is testing may actually use the mechanical sensing technique. Since he is waiting for Medtronic to list him as an inventor on Denniston's dual sensing patent, Mirowski may not want to tip his hat that he would be needing that dual sensing patent.

A patent may be issued to Medtronic on a technique developed by Bill Engle and Dennis Hepp for inhibition by the patient of false positive trigger signals. This is an invention [p. 5364] that helps further reduce the possibility of false discharge. The patient is alerted by a beeper or by skin stimulation if the AID has determined that fibrillation is present. The patient can then place a magnet over the AID to inhibit the unit from discharging. The patient would lose consciousness within 15 seconds and would no longer inhibit the AID if he is in fibrillation. If the patient retains consciousness he is not fibrillating and can continue to inhibit the AID. This concept adds another source of reliability.

Bill Engle has disclosed another invention which enables noninvasively determining if the AID has been discharged. This will be useful if a patient dies to determine if the AID attempted defibrillation.

Although Medtronic is not in a powerful bargaining position from a patent standpoint with Mirowski and Medrad, we do have at least one patent which may be of interest to them, as well as two other possibilities. Medtronic does have substantial bargaining power from the standpoint of our marketing/technical/manufacturing and distribution capabilities. Medrad/Mirowski must be made aware of these factors in our negotiations.

PX-1404

MODEL 7215 INVESTIGATIONAL PLAN

[Vol. 4, p. 1]

A. STUDY PURPOSE

1. Name and Intended Use of System

The Model 7215 PCD (Pacer-Cardioverter-Defibrillator) is an implantable, multiprogrammable, automatic tachyarrhythmia control device designed to detect and treat episodes of ventricular tachycardia (VT) and ventricular fibrillation (VF). Cardioversion and defibrillation pulses are delivered via a three-electrode system consisting of a combination of epicardial patch electrodes (Models 6891 and 6892). Pacing therapies, both bradycardia (VVI) and tachycardia, and sensing will be accomplished using a bipolar electrode configuration consisting of a standard, commercially-available myocardial pacing electrode and one (1) of the epicardial patch electrodes. Programming and interrogation of the Model 7215 will be performed using the Model 9785 Memory Mod software cartridge in conjunction with the Model 9710 programmer.

Criteria for detection of episodes of ventricular tachycardia are independent of detection criteria for ventricular fibrillation. Up to four (4) independently programmable VT therapies may be chosen and automatically delivered from among two (2) overdrive pacing modes, burst and ramp, and cardioversion. Likewise, up to four (4) programmable VF therapies, all defibrillation pulses, may be automatically delivered after VF detection by the Model

7215. Pacing, cardioversion, and defibrillation therapies may also be delivered manually by the physician via the programmer.

The PCD system is intended for use in patients at risk of sudden cardiac death due to ventricular tachyarrhythmias which have been shown to be terminated reliably and, in the case of VF, terminated at an energy level below the maximum output energy of the Model 7215. Patients will either have survived a previous cardiac arrest associated with ventricular tachyarrhythmia and not associated with a recent myocardial infarction or have recurrent, sustained ventricular tachyarrhythmias despite acceptable drug therapy.

Experience with intracavitary cardioversion/defibrillation using a single pulse has been previously reported (Medtronic IDE for Intracavitary Cardioversion #G820095). Subsequent studies suggested, using a three-electrode system to deliver two (2) defibrillation pulses over two (2) separate pathways in a sequential fashion, that defibrillation could be accomplished with lower voltage and energy than that required for a single pulse delivered across a single pathway.

[Vol. 4, p. 2]

The proposed study within this protocol examines this concept of sequential pulse cardioversion/defibrillation as well as pacing therapies for VT and algorithms for the automatic detection of VT and VF. This study builds on the previous animal and acute human studies on sequential pulse cardioversion/defibrillation of Bourland, Jones, Klein, Kallok, and Zipes; evaluation of decremental overdrive pacing techniques by Charos, Haffajee, and Den Dulk; and studies on tachyarrhythmia detection algorithms by Bardy and Olson. The current study will examine the application of these concepts using a totally implantable system.

2. Study Objectives

This study is designed to evaluate the operation, safety, and effectiveness of the design concepts used in the Model

7215 PCD tachyarrhythmia control device and its associated lead system in detecting and treating episodes of ventricular tachycardia and ventricular fibrillation, emphasizing sequential pulse defibrillation for treatment of VF.

This clinical investigation will consist of a single phase that will require strict patient selection criteria, and careful pre- and post-implant evaluation to ensure maximum patient safety and optimal device performance.

The data will be reviewed by the Clinical Study Monitor, by the Study Medical Consultants and/or all investigators and the Study Research Advisor, Michael Kallok, Ph.D. Reviews will be conducted to determine if there are any significant safety or efficacy issues identified during the evaluation of the Model 7215.

Objectives for the study are:

- to research the design concepts used in the Model 7215 tachyarrhythmia control device and its associated lead system in detecting and treating episodes of ventricular tachycardia and ventricular fibrillation;
- to monitor the effect of the Model 7215 on the rate of sudden cardiac death defined as an unexpected death occurring within one hour of the onset of symptoms;
- to identify patient populations that may benefit from devices incorporating features similar to the Model 7215, and to establish criteria for selecting those patients most likely to benefit.

Data will be collected to meet the objectives cited above. These data will be utilized for Medtronic requirements, and may be used for future regulatory submissions. It is anticipated that the Model 7215 PCD as presently configured will not be market released. Performance of this device and its associated lead system may provide valid support for the next generation PCD device, Model 7216, presently under development.

TX-1426

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

RECEIVED
NOV -5 1987

OCT 30 1987

Mr. Timothy J. Johnson
Product Regulation Manager
New Products Management
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432

Re: IDE Number G870102/A1
Model 7215 Multiprogrammable Tachyarrhythmia
Control System
Dated: October 2, 1987
Received: October 3, 1987

Dear Mr. Johnson:

The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. Your application is conditionally approved, and you may begin your investigation at the institutions listed in the enclosure after you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to 13 institutions and 30 subjects.

This approval is being granted on the condition that, within 30 days from the date of this letter, you submit information correcting the following deficiencies:

1. Based on your studies, please provide a comparison between the previous lead Models 6885, 6888, 6889, 6890 and the 6891, 6892, and the 6893 leads during sequential

pulse delivery in terms of design/construction, the amount of energy delivered as a function of voltage, impedance, pulse duration and the amount of necrotic tissue observed. The current density and uniformity of the named leads should also be discussed.

2. The results of studies that assess ventricular fibrillation (VF) sensing, electrogram signals and defibrillation threshold after multiple shocks should be provided.
3. You should submit a written confirmation that the lead Model 4951 will not be used in the Model 7215 study until further notice as discussed.
4. The informed consent should note that five leads will be implanted.

Page 2 - Mr. Timothy J. Johnson

5. The flex test results of the models 6891, 6892 and 6893 leads should be analyzed in light of the physiological environment and the requirements for epicardial leads. The expected flex areas on the leads and adapters and the design elements which will minimize the susceptibility should be identified.
6. A plan for evaluating defibrillation threshold, VF sensing and pacing thresholds at follow-up should be submitted.
7. Your proposed plan of study for evaluating the model 6893 lead in vivo should be submitted. At this time the 6893 lead is not approved for the clinical study.
8. Data that verify shelf life package integrity of the leads and pulse generator should be provided.
9. A description of the design and test data of the lithium thionyl chloride cells that are applicable in the prevention of forced overdischarge should be provided. What is the predicted duration of the elective replacement period for the lithium thionyl chloride cells?
10. The accuracy of the telemetered measurements should be included in the labeling.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

If you do not provide this information within 30 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE application does not imply that this investigation will develop sufficient data to assure a determination of substantial equivalence of a premarket notification (510(k)) submission or sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance of their toll free number (800) 638-2041 or (301) 443-6597.

Page 3 - Mr. Timothy J. Johnson

We have enclosed the guidance documents entitled "Sponsor Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor. Please contact the individuals listed below if you have any questions regarding these responsibilities.

If you have any questions, please contact Mrs. Doris Terry at (301) 427-7594 or Mr. Timothy A. Ulatowski at (301) 427-8162.

Sincerely yours,

/s/ KSHITIJ MOHAN

Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

PHYSICIAN

- Gust Bardy, M.D.
1. Harborview Med. Ctr./
Seattle
- Ross Fletcher, M.D.
2. V.A. Hospital/
Washington, DC
- Charles Haffajee, M.D.
3. Univ. of MA/
Worcester, MA
- Mark Josephson, M.D.
4. Univ. of PA/
Philadelphia, PA
- Rodolphe Ruffy, M.D.
5. Jewish Hospital/
St. Louis, MO
- Sanjeev Saksena, M.D.
6. Newark Beth Israel/
Newark, NJ
- Scott Spielman, M.D.
7. Albert-Einstein - North
8. Temple Univ./
Philadelphia, PA
- Paul Troup, M.D.
9. Med. Coll. WI/
Milwaukee, WI
- Roger Winkle, M.D.
10. Sequoia Hospital/
Palo Alto, CA
- Chris Wyndham, M.D.
11. Methodist Hospital/
Houston, TX
- Douglas P. Zipes, M.D.
12. Indiana Univ. Hospital
13. Veterans Administration Hosp./
Indianapolis, IN

IRB CHAIRPERSON

- Charles Buffington
- Louis Korman, M.D.
- Marcia K. Liepman, M.D.
- Ruth Clark
- Steve Teitelbaum, M.D.
- Lester Goldman, M.D.
- Sidney Cohen, M.D.
- Peter Chapman, M.D.
- Fred Marcus, M.D.
- Frank Smith, M.D.
- Conrad Johnston, M.D.

**SPONSOR RESPONSIBILITIES
FOR A
SIGNIFICANT RISK DEVICE INVESTIGATION**

GENERAL DUTIES (21 CFR 812.40):

1. Submitting the IDE application to FDA
2. Obtaining both FDA and IRB approvals and submitting certification of IRB approval to FDA before shipping the device to any investigator
3. Obtaining FDA approval and IRB approval for a supplemental application before beginning that portion of the investigation
4. Selection of investigators
5. Ensuring proper monitoring
6. Ensuring patient informed consent is obtained

SELECTION OF INVESTIGATORS (21 CFR 812.43):

1. Assuring selection of investigators qualified by training and experience
2. Shipping the investigational device only to participating investigators
3. Obtaining a signed investigator's agreement containing:
 - a. investigator's curriculum vitae
 - b. statement of investigator's relevant experience, including dates, location, extent, and type of experience
 - c. if an investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to the termination
 - d. statement of the investigator's commitment to:
 - (1) conduct the investigation in accordance with the agreement, the investigational plan, Parts 50, 56, and 812, and any conditions of approval imposed by the IRB or FDA

- (2) supervise all testing of the device involving human subjects
 - (3) ensuring that the requirements for informed consent, Part 50 are met
4. Providing investigators with the necessary information to conduct the investigation including, but not necessarily limited to:
 - a. the investigational plan
 - b. the report of prior investigations

MONITORING (21 CFR 812.46):

1. Selecting monitor(s) qualified by training and experience to monitor the progress of the investigation
2. Securing compliance of all investigators in accordance with the signed investigator's agreement (see above for contents of that agreement), or discontinue shipment and terminate the investigator's participation in the investigation
3. Ensuring that significant new information about the investigation is provided to all reviewing IRBs, FDA, and investigators
4. Evaluating all unanticipated adverse device effects and terminating the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. Reporting requirements are listed below.
5. Resuming terminated investigations only after both FDA and IRB approvals are obtained.

SUPPLEMENTAL APPLICATIONS (21 CFR 812.35(a) and (b)):

Supplemental applications are required to be submitted to, and approved by, FDA in the following situations:

1. Changes in the investigational plan: FDA approval is required for any change that may affect the scientific soundness of the investigation or the rights, safety or welfare of the subjects. IRB approval is also required for changes

that may affect the rights, safety or welfare of the subjects. The change in the investigational plan may not be implemented until both FDA and IRB approvals are obtained.

2. Addition of new institutions: IRB approval is also required for new institutions. The investigation at new institutions may not begin until both FDA and IRB approvals are obtained, and certification of IRB approval is submitted to FDA.

MAINTAINING RECORDS (21 CFR 812.140(b)): (see Table I, next page)

1. Correspondence (including reports) with another sponsor, monitor, investigators, an IRB or FDA
2. Records of shipment, including:
 - a. name and address of consignee
 - b. type and quantity of device
 - c. date of shipment
 - d. batch numbers or code marks
3. Records of disposition, describing:
 - a. Batch number or code mark of devices returned, repaired, or disposed of by the investigator or other persons
 - b. Reasons for and method of disposal
4. Signed investigator agreements
5. Adverse device effects (whether anticipated or unanticipated) and complaints

Table I
Responsibilities For Preparing and Submitting
Reports For Nonsignificant Risk Devices

____Report Prepared By____		
Type Of Report	Investigators For	Sponsors For
Unanticipated Adverse Effect Evaluation	Sponsors and IRBs	FDA Investigators and IRBs
Withdrawal of IRB Approval	Sponsors	FDA Investigators and IRBs
Progress Report	N/A	IRBS
Final Report	N/A	IRBs
Inability to Obtain Informed Consent	Sponsors and IRBs	FDA
Withdrawal of FDA Approval	N/A	IRBs and Investigators
Recall and Device Disposition	N/A	FDA and IRBs
Significant Risk Determinations	N/A	FDA

SUBMITTING REPORTS (21 CFR 812.150 (b)):
 (see Table II below)

1. Unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. Subsequent reports on the effect may be required by FDA
2. Withdrawal of IRB approval
3. Withdrawal of FDA approval
4. Current 6-month investigator list
5. Annual progress report — see attached format for IDE progress report
6. Recall and device disposition

7. Final report - See attached format for progress reports
8. Use of device without obtaining patient informed consent
9. Significant risk determinations by the IRB when proposed to be nonsignificant risk
10. Other reports requested by the IRB or FDA

Table II
Responsibilities For Preparing and Submitting Reports
For Significant Risk Devices

____Report Prepared By____		
Type Of Report	Investigators For	Sponsors For
Unanticipated Adverse Effect Evaluation	Sponsors and IRBs	FDA Investigators and IRBs
Withdrawal of IRB Approval	Sponsors	FDA Investigators and IRBs
Progress Report	Sponsors, Monitors and IRBs	FDA and IRBs
Final Report	Sponsors and IRBs	FDA Investigators and IRBs
Emergencies (Protocol Deviations)	Sponsors and IRBs	FDA
Inability to Obtain Informed Consent	Sponsors and IRBs	FDA
Withdrawal of FDA Approval	N/A	IRBs and Investigators
Current Investigator List	N/A	FDA
Recall and Device Disposition	N/A	FDA and IRBs
Records Maintenance Transfer	FDA	FDA
Significant Risk Determinations	N/A	FDA

Suggested Format for IDE Progress Reports

I. The Basics

- IDE Number
- Device name and indication for use
- Sponsor's name, address and phone number
- Contact person

II. Study Progress

(Data from beginning of the study should be reported, unless otherwise indicated.)

- Brief summary of study progress in relation to investigational plan
- Number of investigators/investigational sites (attach list of investigators)
- Number of subjects enrolled (by indication or model)
- Number of devices shipped
- Brief summary of results
- Summary of anticipated and unanticipated adverse effects
- Description of any deviations from the investigational plan by investigators (since last progress report)

III. Risk Analysis

- Summary of any new adverse information (since last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
- Reprints of any articles published from data collected from this study
- New risk analysis, if necessary, based on new information and on study progress

IV. Other Changes

- Summary of any changes in manufacturing practices and quality control (including changes not reported in a supplemental application)
- Summary of all changes in investigational plan not required to be submitted in a supplemental application

V. Future Plans

- Progress toward product approval, with projected date of PMA or 510(k) submission
- Any plans to change investigation, e.g. to expand study size or indications, to discontinue portions of the investigation or to change manufacturing practices
(NOTE: Actual proposals for change should be made in a separate supplemental application).

S 3390 CONGRESSIONAL RECORD—SENATE

April 5, 1989

MEDICAL TECHNOLOGY COMPETITIVENESS ACT OF 1989

Mr. DeCONCINI. Mr. President, I take this occasion to inform my colleagues of a recent judicial decision that appears to eliminate the necessity for enacting S. 622, the Medical Technology Competitiveness Act of 1989, which I introduced on March 16.

Last week, the U.S. Court of Appeals for the Federal Circuit [CAFC] ruled that the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, permits clinical testing of medical devices during the term of an unexpired patent so long as the purpose of the testing is for submission to the U.S. Food and Drug Administration. The decision of the court thus gives the same protections and permissions to medical devices as are allowed for human drugs under Public Law 98-417.

The CAFC stated that medical devices were implicitly covered by Public Law 98-417. I agree with that decision. As I indicated when I introduced S. 622, the purpose of my bill was to clarify and to make explicit what the CAFC now says the law is. Therefore, there is no need for further legislation. I have canceled our subcommittee hearings on S. 622 which had been scheduled for April 13.

Let me take this opportunity to thank my colleagues—MR. DURENBERGER, MR. ADAMS, and MR. GORTON—for being original cosponsors of S.622. None of us desired to take sides in any legal

disputes but we felt it important to clarify Public Law 98-417 so that devices are treated explicitly under the law the same as drugs. We felt this was necessary in order to restore the proper balance in our patent laws between the rights of patent holders and the public need for technological innovation and increased competition.

**35 U.S.C. §271(e)(1) As Enacted in the Drug Price
Competition and Patent Term Restoration Act of 1984,
P.L. 98-417**

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

**35 U.S.C. §271(e)(1) As Amended in 1988 by the Generic
Animal Drug and Patent Term Restoration Act,
P.L. 100-670**

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.